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Office of Water Quality Management Plan

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Office of Water
Office of Water Quality Assurance Management Plan Approvals

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Foreword

Most U.S. Environmental Protection Agency (EPA) activities involve some form of environmental data, including the collection of data by EPA and the development of regulations requiring that others collect environmental data. As a result, in 1979, EPA established a policy that requires all of its component organizations to participate in an agency-wide quality system. EPA Order 5360.1 A2, dated May 5, 2000, is the most recent version of the policy and program requirements for the EPA quality system. The order defines a quality system as:

> *"A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products, and services."*

The EPA quality system requirements have evolved since 1979 and now incorporate a national consensus standard for quality systems authorized by the American National Standards Institute (ANSI) and developed by the American Society for Quality Control (ASQC), ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* The Quality Staff in the Office of Environmental Information also develop documents that outline the specific requirements for the EPA quality system and that provide guidance on its implementation (see the reference section of this document).

Among other things, the EPA order requires that each organization prepare a document called a quality management plan (QMP) that:

- documents the organization's quality policy,
- describes its quality system, and
- identifies the environmental programs to which the quality system applies.

This document is the quality management plan for the entire EPA Office of Water. It describes the quality system used by the Office of Water and applies to all environmental programs within the Office of Water and to any activity within those programs that involves the collection or use of environmental data. This quality management plan supersedes the one approved by the Office of Water in 1995. It incorporates many of the long-established procedures used to successfully manage quality in the Office of Water and provides a practical approach to meeting the expanded goals of the EPA agency-wide quality system in the 21st century.

A major goal of this plan is to provide a description of the quality system that is of value to the users in the Office of Water. The *EPA Requirements for Quality Management Plans* (EPA QA/R-2) is the policy document containing the specifications and requirements for quality management plans and it includes 10 elements of a quality system that must be addressed in a quality management plan. The Office of Water quality management plan addresses each of the 10 elements to the extent to which they apply. However, to promote the understanding and use of the plan, it has been written from the perspective of the Office of Water staff who will implement it. In addition, the plan avoids the use of jargon whenever possible and it is not structured directly around the 10 elements.

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Chapter 1
Introduction

The Office of Water is committed to ensuring the quality of all of its activities and decision-making processes. This document is the quality management plan for the Office of Water and all of its component parts. This plan describes the management and technical practices that are used to assure that the environmental data used by all programs within the Office of Water to support decisions are of adequate quality for their intended purpose. We refer to this collection of procedures and activities as our "quality system." It is designed to provide decision makers in the Office of Water with a practical framework for managing the quality of all activities within the Office.

Quality management is the part of an organization's overall management system that determines the requirements for quality up front and implements the policies and procedures needed to ensure that the quality requirements for the organization's products are continuously met. The Office of Water recognizes that there cannot be a one-size-fits-all approach to every activity. Therefore, the basic tenet of the Office of Water's quality system is shown to the right. This tenet is a guiding principle which applies throughout this quality management plan.

Basic Tenet of the Quality System

The level of effort needed to manage the quality of any activity depends on:

- **the importance of the activity,**
- **the risk of a decision error,**
- **the schedule for completion, and**
- **the available resources.**

In addition to its commitment to quality in *all* of its activities, the Office of Water relies on environmental data in its daily activities and decision-making processes. Accordingly, the Office of Water is committed to ensuring the quality of the data on which these decisions are based, and has established a goal concerning the quality of data used within the Office.

Goal for Data Quality

Environmental decisions shall be based on data of known and documented quality, such that the decisions are scientifically, and where necessary, legally defensible and able to withstand public scrutiny.

Quality Policy

The Office of Water has established a quality policy that is based on this basic tenet and the goal for data quality. The policy provides a succinct statement of the scope of the quality system and the components of the quality policy guide the specifics of this plan. The quality policy stresses the need for systematic up-front planning and the use of a graded approach to quality management that conforms to the basic tenet listed above. The Office of Water's quality policy is summarized in **Exhibit 1**.

Exhibit 1
Office of Water Quality Policy

- **The quality system is not optional.** It is a critical aspect of all activities in the Office of Water that involve the generation and use of environmental data and quality is built into these activities from the start. It applies to activities conducted by the Office of Water, its contractors and grantees, and to those programs delegated to States and Tribes.

- **All staff in the Office of Water have a responsibility for the quality of their work and of the organization.** The responsibility is fostered by clear communication of the goals and requirements of the quality system to all staff, as well as appropriate quality-related training.

- **There is an individual identified within each organizational unit** in the Office of Water who is the focal point for the implementation of the quality system within that unit and **whose quality system activities are independent of the line management structure.**

- **Quality is a critical responsibility of *all* levels of management within Office of Water** and all management personnel have identifiable roles in the quality system. Managers are responsible for ensuring the allocation of funding for quality management activities, including intramural, extramural, and travel funds, as well as funding for personnel and quality-related training.

- **Quality can only be achieved through systematic planning, assessment, and corrective action.** Management is responsible for ensuring that adequate staff and other resources are devoted to these aspects of every project.

- **The importance of the project, the risk of a decision error, the schedule for completion, and the available resources are used to establish the level of quality management applied to a given activity.** These considerations must be addressed and documented during the planning phase of the activity.

- **The quality of any environmental data or information used by the Office of Water must be assessed (known) and documented,** regardless of the source. Managers and decision makers are responsible for ensuring that the results of those assessments are considered in the decision-making process.

- **All environmental decisions made by the Office of Water must be evaluated relative to the quality of the underlying data and information and these evaluations must be documented.** Where the quality of the data or information cannot be controlled by the user (e.g., data from sources outside of the Office of Water) or does not meet the objectives set during the planning phase, the decision will be adjusted accordingly.

Graded Approach

The graded approach to quality management may be the most important aspect of this plan and it will apply to virtually all parts of the quality system. The basic philosophy behind the graded approach is to recognize that "quality" is not an objective attribute that remains constant. Rather, quality is a subjective attribute of a process or product that must be established *in the context of the use of that process or product.* Environmental data are the products of many activities within the Office of Water. Environmental decisions are also products, and they often are based on environmental data. Therefore, the quality of the data and the effort to manage the quality of the data and the decisions should be based on the end goal of the decision.

Not all decisions based on environmental data require the same numerical certainty in the underlying results. Some decisions involve a greater risk if the decision is in error, for example, the risk to public health if the level of a contaminant in drinking water is not adequately controlled.

"Good" quality data are those data that enable the user to make the decision at hand with an acceptable risk of error and in the time frame required.

Moreover, most environmental decisions made by the Office of Water are associated with some schedule or deadline. These schedules and deadlines may be driven by legislative requirements, judicial decisions or consent decrees, funding priorities, or even emergency situations involving environmental accidents. Thus, as noted above, "good" quality data allow the decision to be made in the time frame required. Conversely, data that arrive too late to make the decision may be of little or no value at all, regardless of any other measures of their quality.

This plan provides the Office of Water with an explicit mechanism to apply a graded approach to strike a balance among the importance of the activity, the risk of a decision error, the schedule for completion, and the available resources, when managing the quality of any activity involving environmental decision making.

Limitations of the Plan

This plan is a policy document and it cannot:

- Be overly prescriptive, but will use examples and tools to provide context so that the user can tailor the system to specific needs
- Provide specific solutions, but will describe a general process and tools that can be used to support quality management activities
- Provide guidance for every situation or apply a single approach to all activities - it is a description of the general approach needed to implement the Office of Water's quality policy

How the Plan Affects You

This plan describes how you can manage the quality of your daily activities. While managers and other staff may have specific roles in the quality system that are described in this plan, all staff in the Office of Water play *some* role. If you are involved in the collection, evaluation, or use of environmental data, this plan describes activities that are essential to meeting the Agency-wide requirements for quality. Therefore, all Office of Water staff are urged to:

1. Read the plan
2. Identify your role in any data collection and environmental decision-making activities
3. Identify the people in your organization with specific quality system roles, including managers and quality system contacts, and your organizational relationships to them
4. Discuss the plan and any questions you have with your supervisors and line managers

As an EPA contractor or a grantee, many aspects of this plan will flow down to your organization in terms of specific contract or grant requirements to address quality. Therefore, you should follow the same four steps listed above.

How the Plan is Organized

This plan addresses all 10 of the required elements for an EPA quality system. However, in order to promote the understanding and use of the document by the staff, it is written from the perspective of an employee in the Office of Water, not a quality system specialist. Therefore, it is not rigidly organized around those 10 elements.

- Chapter 1 is the introduction and includes the Office of Water quality policy statement.
- Chapter 2 defines the types of environmental data and activities that are covered by this plan.
- Chapter 3 identifies staff and management responsibilities for implementing this plan.
- Chapter 4 provides an in-depth discussion of the tools and procedures used to implement the plan.
- Chapter 5 describes the importance of documenting quality system activities.
- Chapter 6 describes the management of quality system documentation and records.
- Chapter 7 describes our commitment to providing training that will allow for successful implementation of this plan.
- Chapter 8 describes the quality system requirements for computer hardware and software.
- Chapter 9 addresses procurement and financial assistance.
- The Reference section lists EPA quality system guidance and requirements documents.

The plan also includes a series of attachments that are checklists that may aid staff in the Office of Water in carrying out the requirements of the quality system and documenting those activities. These checklists include:

- Office of Water Project Quality System Documentation Checklist
- Generic Quality Assurance Project Plan Checklist
- Two attachments to Procurement Policy Notice 01-02, issued by the EPA Office of Acquisition Management in March 2001.
- Quality Assurance Review Form for Extramural Projects
- CMD-Cincinnati Work Assignment Review Checklist

Chapter 2
Definition of Environmental Data

The focus of the quality system requirements in EPA Order 5360.1 A2 is on environmental data. In the past, this was often misunderstood to simply mean chemical measurement data collected in the field or in a laboratory, and most quality system documents focused almost exclusively on procedures for assessing the quality of such data. The latest Agency-wide order concerning quality makes it clear that the quality system must address more than just measurement data.

> ***Environmental data - Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.*** EPA Order 5360.1 A2, May 2000

The focus of this quality management plan is on environmental data, whether they are **collected from measurements, produced from models, or compiled from other sources**. Environmental technologies are covered in the event that the Office of Water is involved.

Types or Sources of Data

Many EPA organizations, including the Office of Water, distinguish between "primary uses" of data and "secondary uses" of data, or "primary data" and "secondary data." For the purposes of this plan, the **primary use** of data is defined to the right. The association of the data with the decision at hand is a critical distinction in the context of this quality management plan. If the data are associated with a decision to be made by the Office of Water, then those data are covered by this plan. Examples of primary data include, but are not limited to:

> **Primary use** of data refers to the use of data that are collected by the Office of Water, or under its direction (e.g., by contractors, grantees, or others) for a specific purpose associated with the decision at hand.

- Field or laboratory data involving the physical, chemical, or biological characteristics of environmental samples
- Data on the physical location of such samples, including latitude, longitude, city, county, state
- Field or laboratory data used to assess the performance of treatment systems or technologies
- Financial information associated with the development of rules, regulations, or guidance documents
- Engineering and process data
- Results produced from models

When primary data are collected by the Office of Water, the collection activities must be planned with quality in mind, and **the quality of the primary data must be assessed** against the needs of the project. Chapter 4 of this quality management plan describes procedures for planning, implementing, evaluating, and improving the quality of any activity, including the collection of primary data.

What often distinguishes primary use of data from secondary use is the control that the Office of Water exerts on the generation of the data. This includes the ability to require that the information needed to assess the quality of the data be generated along with the data and delivered to the Office of Water. The control exerted by the Office of Water is often a function of the fact that the Office of Water is paying for the data to be generated, but may also come into play where the Office of Water has direct approval authority for the generation of data by an external party.

The Office of Water uses the term **secondary use**, as defined to the right. Other terms such as "acquired data," and "data from other sources" have been used to express the same concept. Secondary data may include:

Secondary use of data refers to data that were *not* directly generated by the Office of Water to support the decision at hand.

- Data collected by someone other than the Office of Water and not under the Office of Water's control
- Data collected by the Office of Water or others for some other purpose than the current intended use
- Data compiled from a variety of sources and published in the literature
- Anecdotal information not collected in any organized fashion

This quality management plan is designed to encourage secondary use of data, where appropriate. The secondary use of existing data can preserve budget resources by avoiding redundant data collection activities within the Office of Water and across EPA programs. However, the challenge in using existing data is that their generation is often outside of the Office of Water's control, and as a result, the Office cannot directly manage or control the quality of the data. If the Office of Water lacks the ability to control the quality of the data, then assessing the quality of the data becomes even more important. When the Office of Water uses data that started as primary data generated by another program within the Office of Water or another part of EPA, the quality of the data may be easy to determine by examining the documentation that was produced with the data. In other cases, the data may have to be examined in terms of who originally produced them and the quality may have to be inferred by less direct means. **Whatever the source, the quality of secondary data must be assessed.** Chapter 4 describes planning procedures for any data collection activity, including planning how secondary data may be assessed and used in a manner that provides an acceptable level of risk in making environmental decisions.

The graded approach applies to the quality of environmental data as well. The decision makers and planners must recognize that the quality of data must be defined by the use, and therefore, the decision to be made. It is critical to plan for the use of data from either primary or secondary sources, but the degree of planning and the quality of the data needed should be based on the **importance of the project, the risk of a decision error, the schedule for completion, and the available resources**. Examples of the subjective nature of quality and the use of a graded approach are provided below.

Americans face risks of illness from swimming and other recreational activities in coastal areas, lakes, and rivers that are contaminated with disease-causing microbes. Many of the beaches and lakes are monitored for conditions that present a threat to human health. When the conditions warrant, an advisory may be issued or a beach may closed to swimming. The decision can be expressed as *"Should an advisory be issued or should a beach be closed?"* The data used to make the decision may come from a routine monitoring program. A series of water samples is collected over a 30-day period and analyzed for enterococci, an indicator of sewage contamination. EPA established numerical guidelines for enterococci in water that address the mean concentration of the organism in the samples as well as a statistical protocol for evaluating the results. If the monitoring results exceed the guidelines, then an advisory may be issued or the beach closed. The data require a high degree of quality management. A monitoring program must be designed and implemented, samplers trained, a microbiological laboratory must be hired, and statistical evaluations of the data must be made. This is a significant commitment of time and effort to protect the potential users of the beach from possible exposure and infection.

In contrast, imagine that heavy rains entering a combined sewer system cause large lumps of untreated sewage to wash onto the beach. The decision remains the same, *"Should an advisory be issued, should a beach be closed?"* However, the untreated sewage is visually apparent and is sufficient evidence of a problem without collecting samples or performing statistical analyses. The threat to human health is immediate. Therefore, the visual observations of lifeguards with minimal scientific training provide data that are of good quality for *this* decision. More importantly, the decision can be made on the schedule required, i.e., *immediately*. Thus, using the graded approach, the decision to close the beach is made without as much effort to manage the quality of the data.

Chapter 3
Organization and Management of the Quality System

This chapter provides a brief overview of the Office of Water organizational structure and a detailed description of the Office of Water's quality system, including responsibilities within that system. As an Office of Water employee, you need to understand your responsibilities for implementing this plan. For ease of reference, responsibilities are divided into two areas: program staff who are responsible for managing and implementing projects within the Office of Water and quality system staff who are responsible for assisting with and overseeing quality management activities. A third section focuses on the unique set of roles and responsibilities required to manage quality in programs which are delegated to Regions, States, and Tribal governments.

Organization of the Office of Water

The mission of the Office of Water is to protect the nation's water resources. To accomplish this mission, the Office of Water is divided into five major program offices. Each program office, other than the American Indian Environmental Office, is divided into two or more divisions, and most of those divisions are subdivided into two or more branches (see **Exhibit 2**). Because the branches are the origin of many of the decisions that are based on environmental data, they also form the basis for the structure of the Office of Water quality system. The five program offices are:

- American Indian Environmental Office (AIEO),
- Office of Ground Water and Drinking Water (OGWDW),
- Office of Science and Technology (OST),
- Office of Wastewater Management (OWM), and
- Office of Wetlands, Oceans, and Watersheds (OWOW).

The program offices are currently supported by:

- Management and Operations Division,
- Water Policy Division,
- Resource Management Division, and
- the Communications Team.

These three staff divisions and the communications team do not have an active role of their own in environmental decision-making. As a result, the support that they provide to the rest of the Office of Water is not specifically addressed in this quality management plan. However, the principles of the Office of Water quality system still apply and staff in these divisions are encouraged to apply them to their daily activities.

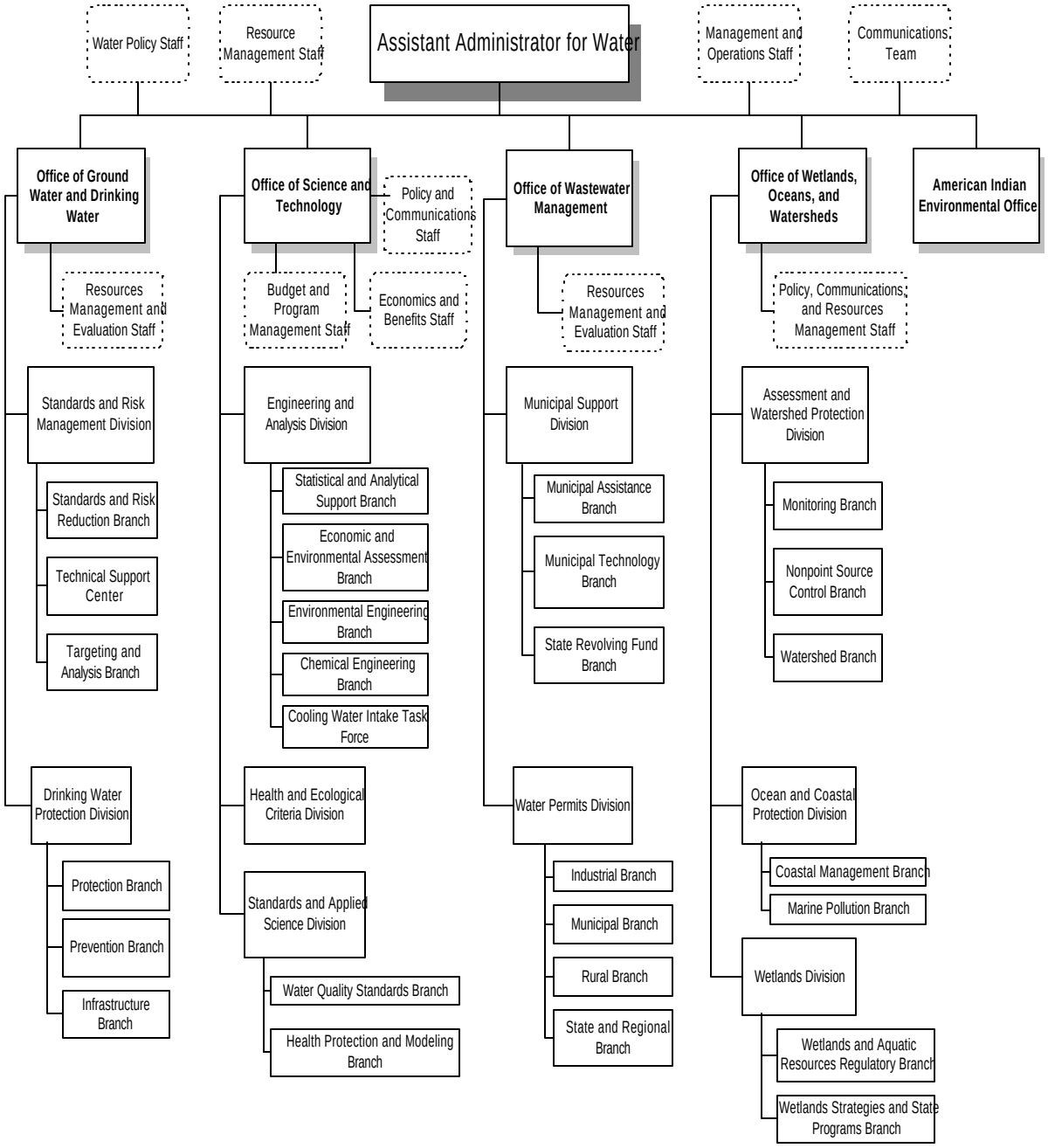
Organization of the Quality System

A fundamental principle of any quality system is that the system must receive direction from the top down and be implemented from the bottom up. A quality system cannot be imposed on any organization from above, nor overlaid on the organization without being incorporated into the organization's culture.

Accordingly, *everyone* in the Office of Water has some role to play in ensuring the quality of the products of the Office of Water and everyone has a responsibility to do their best. However, there are a small number of individuals with specific roles which must be fulfilled *within the quality system itself*.

"If you're not part of the solution, you're part of the problem"

Exhibit 2
Office of Water Organization Chart



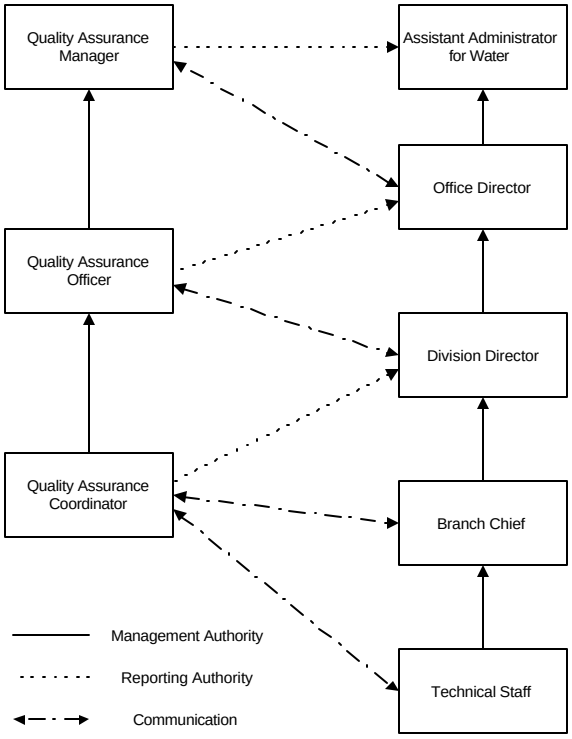
The roles of these individuals are divided into two "tracks," one specifically for program staff, and the other for those who specialize in managing the quality system itself, as shown in **Exhibit 3**.

Note: If a Division has no branches, then the role of the Branch Chief may be filled by an Associate Division Director. In addition, within some parts of the Office of Water, the Quality Assurance Coordinator may be assigned at the Division level, rather than the Branch level. In these instances, the Quality Assurance Coordinator will function at the Division level.

Contrary to common perception, the purpose of the two tracks is *not* to separate the responsibility for quality from the routine management activities. Rather, the separate track for the quality system staff is designed to ensure that the *management of the quality system itself is independent of routine management.*

The staff within the quality system are responsible for the day-to-day functioning of the quality system. In order to do that effectively, these positions function independently of the line management structure. *This is another fundamental tenet of any quality system.*

Exhibit 3
Generic Quality System
Organizational Structure



The solid lines indicate management authority within each track. The dotted lines indicate reporting authority between the two tracks. As indicated, the staff in quality system roles report information on the status and success of the quality system to the management level above the one in which they function. Finally, there are lines of communication between both tracks at every level. The communication lines are shown with arrows at each end to emphasize the need for communications in both directions.

Program Staff Responsibilities

Role of Management

Every member of the management structure within the Office of Water is responsible for *implementing* the quality system. There are costs associated with producing quality work and for managing quality. However, those costs are generally far less than the cost of redoing the work to achieve a quality product or to defend against a poorly-made decision. Managers are responsible for allocating resources (budget and staff) to every project undertaken within their part of the Office and those resources must be sufficient to carry out the technical work and ensure its quality. Managers set schedules and establish priorities, both of which must reflect the demands of quality management. One of the most important functions which the managers perform in the quality system is communication, both up and down the management chain. It is the managers who can communicate the importance of quality within the organization and who can most readily affect its incorporation into the organization's culture. While communications may focus on specific quality problems, managers must also communicate the need for quality training, staff and budget resources, and systematic planning.

The quality system responsibilities of the four levels of management from the Assistant Administrator for Water to the Branch Chiefs are summarized in **Exhibit 4** and are based on the requirements described in EPA Order 5360.1 A2. These managers maintain frequent communication and

work in concert with the quality system staff within the Office of Water to manage the quality system and incorporate it into all environmental decision-making activities within the Office that rely on environmental data. The quality system functions from the bottom up, such that the responsibility at each level of management builds on the efforts of the levels below.

Exhibit 4
Quality System Responsibilities of Office of Water Managers

Management Responsibility	Assist. Admin.	Office Director	Division Director	Branch Chief*
Compliance with the quality system by EPA staff	**M**	**M**	**M**	**M**
Communicating the importance of quality to staff	**M**	**M**	**M**	**M**
Providing adequate resources for the quality system, including training, travel, staff and budgets	**M**	**M**	**M**	**M**
Ensuring that decisions are supported by data of known quality	**M**	**M**	**M**	**M**
Compliance with the quality system by delegated programs	**M**	**M**		
Compliance with the quality system of extramural organizations	**F**	**M**	**M**	
Performance agreements contain quality system standards	**M**	**M**	**M**	**M**
Quality system training is provided to staff	**F**	**M**	**M**	**M**
Systematic planning of all projects within the organization	**F**	**F**	**M**	**M**
Assessment of data quality		**F**	**M**	**M**
Determining the need for quality system training		**F**	**M**	**M**
Participation in systematic planning		**F**	**F**	**M**
Approval of project planning documents			**F**	**M**
Approval of the Office of Water quality management plan	**M**	**M**		
Periodic evaluations are conducted of internal and external organizations	**M**	**M**	**M**	**M**
Documenting quality management activities within the organization	**M**	**M**	**M**	**M**
Sampling, analysis, and data handling procedures meet quality system requirements and are documented, reviewed, and approved			**F**	**M**
Identifying need for SOPs		**F**	**M**	**M**
Ensuring implementation of corrective actions within the organization	**F**	**M**	**M**	**M**

M = Primary management responsibility *In a Division with no Branches, this is the Associate Division Director
F = Oversight responsibility

Roles of Work Assignment Managers and Project Officers

Although they fall outside of the line management chain, Work Assignment Managers, Task Order Managers, and Project Officers play important roles in implementing the quality system, particularly in regard to the activities of contractors and grantees. If you manage activities under a contract or grant, refer to **Exhibit 5** to identify specific responsibilities that you have for implementing the quality system within that vehicle.

Exhibit 5
Quality System Responsibilities of Work Assignment Managers and Project Officers

- Participating with senior program staff and technical personnel in systematic planning for the project, including the development of project objectives, the associated measures of quality, and acceptance criteria (see Chapter 4 and Attachment A)
- Identifying the resources needed for the project, including quality system training needs, and requesting funding from the Branch Chief to meet those needs (see Chapter 4)
- Coordinating with the Quality Assurance Officer in the selection and design of reviews, audits, or other performance evaluations appropriate for the project (see Chapter 4)
- Identifying and implementing project-specific quality management procedures, which may include data quality assessment, information management, data integration, and data validation (see Chapter 4)
- Completing the Quality Assurance Review Form for any extramural projects involving environmental measurements to indicate the quality system requirements that must be included in the development of a Request for Proposal (see Attachments C and D)
- Ensuring that work assignments, work plans, and contract deliverables include quality system documentation appropriate for the activity (see Attachments D and E)
- Preparing and implementing quality system documentation appropriate for the project (see Chapter 5 and Attachment A)

Role of Technical Staff

As noted earlier, quality systems are implemented from the bottom up and all Office of Water staff play a role in the quality system. Technical staff involved in the generation or use of environmental data are responsible for complying with this plan. This includes:

- Reviewing and understanding the quality requirements that are specific to your project(s)
- Implementing and documenting your quality management activities (see Chapters 4 and 5 and the attachments to this plan)
- Reporting any quality management concerns to your supervisor or Quality Assurance Coordinator

Quality System Staff Responsibilities

A hierarchy of quality system staff oversee the implementation of the Office of Water quality system. As shown in Exhibit 3, three specific titles are assigned to staff managing the quality system:

- Quality Assurance Coordinators, typically assigned to each Branch within the Office of Water
- Quality Assurance Officers, assigned to each Program Office
- Quality Assurance Manager, the individual assigned to the Office of Water

Note: Within some parts of the Office of Water, the Quality Assurance Coordinator may be assigned at the Division level, rather than the Branch level. In these instances, the Quality Assurance Coordinator will function at the Division level.

As noted earlier, the roles of these staff are to make sure that the quality system functions on a day-to-day basis. In order to do that effectively, these positions function independently of the line management structure. *This is another fundamental tenet of any quality system.*

Ideally, each of these quality system positions would be staffed by individuals who are able to dedicate 100% of their time to their quality system roles. In reality, the Office of Water must balance the resource constraints of budgets and staff levels against a variety of other factors including legislative mandates and judicial schedules. As a result, most of the staff fulfilling these quality system roles do so only part time, and also fill technical roles within each of their organizations. When performing work within the quality system, they report to management as described in this plan. When performing technical work, they report to the level of management appropriate for the technical work. Therefore, these individuals must ensure that they are not performing reviews associated with the quality system of work to which they made substantive technical contributions. The structure described here provides a sufficient number of Quality Assurance Coordinators to allow them to cross between Branches when needed to avoid such conflicts. Likewise, the Quality Assurance Officers and the Quality Assurance Manager can share and/or delegate responsibilities for certain projects in which one or the other has played a technical role.

Quality Assurance Manager

The Quality Assurance Manager serves as the focal point for implementation of the quality system and is responsible for office-wide quality management efforts through a network of Quality Assurance Officers and Quality Assurance Coordinators located in the program offices. The Quality Assurance Manager reports to the Assistant Administrator for Water on all quality matters, and assists line management in interpreting EPA quality policy and in developing quality policy and procedures for the Office of Water. The Quality Assurance Manager is responsible for all quality management activities including the following:

- Development and revision of the quality management plan
- Development of office-wide quality policies and procedures
- Development of the Quality Assurance Annual Report and Work Plan
- Performing audits and reviews, and oversee the implementation of internal and external quality management evaluations
- With the assistance of the Quality Assurance Officers, oversee the annual review process for all quality system programs including those delegated to Regional offices, States, Tribal, local, and other governmental bodies.
- Serving as the liaison between Office of Water and the Quality Assurance Managers in other programs. This function includes participation in QA conference calls and the Annual National QA Meeting sponsored by the Office of Environmental Information.
- Coordinating Agency-wide and interagency quality functions.

The Quality Assurance Manager has the authority to carry out these responsibilities and to bring to the attention of the Assistant Administrator any issues associated with these responsibilities.

Quality Assurance Officer

The Quality Assurance Officer's primary responsibilities are to oversee all aspects of quality system activities within the Program Office. The Quality Assurance Officer reports directly to the Office Director and the Quality Assurance Manager regarding QA matters.
Specific activities include:

- Recommending or developing approaches needed to manage quality (e.g., manual or automated systems to identify or track the planning, reviewing, and implementation of data collection projects, reviewing results, or documenting project activities)
- Assisting staff scientists and project managers in identifying needs for and developing quality policies and documents and in obtaining answers to technical quality questions
- Assisting the Quality Assurance Manager in interpreting EPA quality policy
- Developing audit materials and performing reviews, audits, and management system reviews

- Providing input to the quality management plan
- Contributing to the Office of Water's Quality Assurance Annual Report and Work Plan
- Participating in the Annual National QA Meeting sponsored by the Office of Environmental Information

The Quality Assurance Officer works closely with management to ensure that:

- Quality system requirements are integrated into Federal regulations and into the programs operated by Regions, as well as State and Tribal governments and the regulated community, to ensure that data of known and documented quality are generated by program offices and their delegated programs
- Audits/reviews are conducted with sufficient depth and frequency to ensure adherence to approved plans, and to identify deficiencies in the quality system
- Appropriate corrective actions are implemented in a timely manner in response to audit/review findings
- All Office of Water personnel, contractors, and grantees who are involved in the collection and use of environmental data have access to needed quality system training or information
- Appropriate quality system requirements are included in all contract solicitations, assistance agreements, and interagency agreements which entail data collection, and that those requirements are met.

Quality Assurance Coordinator

The Quality Assurance Coordinator's major responsibility is to assist the Quality Assurance Officer in the implementation of the quality system. The responsibilities of the Quality Assurance Coordinator are to oversee the day-to-day quality management activities within the Branch (or Division), implement quality system policies under the direction of the Quality Assurance Officer and the Quality Assurance Manager, and serve as the contact person for the technical staff. The Quality Assurance Coordinator reports directly to the Division Director and the Quality Assurance Officer regarding quality management matters. Specific activities include:

- Reporting to management on the status and requirements of the Branch's (or Division's) quality system activities and acting as a conduit for quality management information to Division and Office staff
- Serving as the central point for coordinating all Branch (or Division) quality management activities, including auditing, reviewing, and resolving quality issues
- Reviewing and approving all internal, contractor, and grantee quality system documentation as well as the quality sections of all regulations, program guidance, procurement guidance and grants
- Identifying quality training needs and implementing the training
- Providing guidelines for content and format of quality system documentation, including standard operating procedures, quality assurance project plans, and other planning documents
- Tracking the preparation, review, and approval of quality system documentation
- Preparing requested sections of the Office of Water's Quality Assurance Annual Report and Work Plan and reviewing the quality section of Branch and Division reports

The Quality Assurance Coordinator works closely with line management to ensure that:

- Appropriate planning and quality system documentation are prepared for all activities involving the collection or use of environmental data and are approved in writing by management and quality system staff at the appropriate levels
- Quality system procedures conform to Agency quality system guidance and requirements
- Routinely used procedures that affect data quality are described in standard operating procedures or other appropriate documentation
- Ensuring that all Branch (or Division) personnel receive training in quality system requirements

Delegated Programs - Responsibilities Outside of the EPA Headquarters Structure

Many programs within the Office of Water are delegated to EPA Regions, States, or Tribal governments. Specific quality management responsibilities that reflect the limited role of the Office of Water staff involvement in these activities are defined below. Chapter 9 of this plan also addresses aspects of delegated programs, in the context of using financial assistance (grants and assistance agreements) and project partnership agreements to implement appropriate quality management in such programs.

Activities Delegated to EPA Regions

Office of Water staff work closely with staff in all of the EPA Regions. The relationship between the Office of Water and the EPA Regional offices varies on a program-by-program basis. The Office of Water is responsible for overall policy, guidance, and regulation development. Management of day-to-day activities of Regional water programs is the responsibility of the Directors within each Regional office. Regional Quality Assurance Managers, typically working under the direction of the Regional management officials, develop and oversee implementation of the Regional quality systems. These systems set Regional priorities and policies regarding quality management practices. For programs that are directly implemented by the Region, the Regional quality system takes precedence over the Office of Water quality system in areas where Regional policies and/or procedures are more comprehensive or stringent.

For Office of Water programs delegated to the EPA Regions, oversight and coordination of day-to-day quality management activities are performed by the Regional Quality Assurance Officers or their representatives, including responsibility for assuring that the program participants implement quality management protocols and coordinate their quality system policies with those of the Region.

Notifying the Region of projects that require Regional oversight is accomplished through the financial-assistance and contractual processes described in Chapter 9 of this plan. The responsibilities of the Regional Quality Assurance Officer may include reviewing and approving quality system documentation, planning and performing audits and reviews, reporting audit findings, and training Regional, State, Tribal, local, and other government personnel.

The Office of Water Quality Assurance Officers provide guidance and support to the Regional Quality Assurance Officers in monitoring specific Office of Water programs that have been delegated to Regional offices when requested and/or as needed. These activities may include training, interpreting Office of Water quality system policies, developing guidance documents, and reviewing and approving quality system documentation when requested.

Delegated States, Tribal, Local, and Other Governmental Bodies

In cases where Office of Water programs are delegated to States or Tribal governments, the delegated organization is responsible for implementation of a quality system that complies with EPA quality system policies and guidance from the Regional office. The Regional Quality Assurance Managers or their representatives are responsible for ensuring that every State or Tribe within their Region develops, documents, and implements a quality system that meets the Office of Water, EPA Quality Staff, and Regional requirements. The Regional Quality Assurance Managers are also responsible for review and oversight of State and Tribal government quality systems.

Oversight of Delegated Programs

In accordance with the policies described in the EPA Delegations Manual (1200 TN 390, February 1995), when authority is delegated to an organization other than EPA, that organization is responsible and fully accountable for any actions it takes in exercising that authority. The Office of

Water ensures that delegated programs are implemented according to EPA policy and guidance through the use of a differential oversight policy established in a Performance Partnership Agreement with the State, Tribal, local, or other government body. The Office of Water measures the performance of the delegated program using program results, feedback from stakeholders, and communications between Office of Water staff and the other organization. These communications vary with the nature of the delegated program, program maturity, and available resources, and may include site visits, meetings, and conference calls.

Dispute Resolution

An important aspect of the Office of Water quality system is frequent and open communication among and between the parties with management responsibilities and quality system responsibilities. One goal of those communications is to avoid disputes. However, when issues regarding quality system activities are in dispute, resolution should be sought at the lowest management level practicable. To ensure independence, quality system staff from the next higher level within the organization will assist management in the resolution (e.g, if the issue is to be resolved by a Branch Chief, then the Quality Assurance Officer above that Branch should be involved). Should agreement not be reached at this level, the issue will be resolved by the Office of Water senior management team (Office and Division directors), with the assistance of the Quality Assurance Manager, as needed. The Office of Water Assistant Administrator has final authority to resolve disputes involving Office of Water quality system issues.

Chapter 4
Planning, Implementing, Evaluating, and Improving Quality

The concept of the "quality cycle" was made popular by W. E. Deming in the 1980s. The Office of Water has translated Deming's four components of: *plan, do, check, and act*, into:

- **Planning** projects with quality in mind,
- **Implementing** the project according to plan and making revisions when needed to address unforeseen problems or changes,
- **Evaluating** the quality of interim and final products against the planned goals, and
- **Incorporating lessons learned** into future activities.

Documentation is not considered a distinct phase in the Office of Water quality system. It is an ongoing requirement that you must perform throughout all phases of your project. Indeed, it is often argued that if you did not document your quality management activities, you did not perform them. Because documentation is so important, this plan includes a stand-alone chapter to guide Office of Water managers and staff in documenting their quality management activities (see Chapter 5).

Planning Quality in Office of Water Activities

Just as the three most important principles in real estate are location, location, location, the three most important principles in quality management are **planning, planning, planning!** Because quality must be built into a project at the start, not added later, a crucial requirement of the Office of Water's quality system is the use of up-front, systematic planning for all projects, particularly those that will rely on environmental data of one form or another. Although such projects vary greatly in scope and importance, each should be started in essentially the same way — by determining the relevance of the activity, the level of quality required, and by planning accordingly.

Nobody plans to fail, but many people fail to plan.

The planning steps outlined here are not absolutes, but are a suggested approach to planning that will enable you to plan effectively and meet the requirements of the Office of Water Quality system. Other steps can be taken, other questions asked. The point is that systematic planning is *essential* to managing quality and is carried out by a group with sufficient knowledge to ensure that the relevance of the project and activities undertaken will result in a product that will have the level of quality needed for its intended purpose.

Step 1 - Identify the Project Scope and Purpose

The planning process should begin by addressing the following basic questions:

- What is the primary purpose of the activity?
- How is the activity relevant to our organization's mission, and why is it important to proceed?
- Who is the "customer" for this activity (e.g., senior EPA management, the public, Congress, the regulated community, etc.)"
- What are the customer's requirements?
- Are environmental data required? If so, who are the "suppliers" of those data?
- What are the quality requirements for the activity?
- What is the schedule for completion and is it driven by forces outside of the Office of Water (e.g., legislative or judicial deadlines)?

While the questions need not be in this exact format, the issues behind the questions need to be addressed before proceeding with the activity. A common approach to answering these questions, and thus to planning, is to assemble a team or a work group of knowledgeable staff to work out the details. The project manager should assemble a team that includes members of the management, staff with firm technical grasp of the subject matter, be it environmental chemistry, economics, or statistics, to name just a few, as well as those persons who control the budget and those who manage any contractors or grantees involved in the effort. **It is also essential that the team or work group consult with or seek direction from a member with an assigned quality system role at an appropriate level within the organization, such as the Quality Assurance Coordinator for an activity in a branch, or a Quality Assurance Officer for an activity at the Program Office level.** If a team approach is not employed, it is even more important that a person within the quality system be consulted in the initial planning phase of the activity to ensure that quality system requirements are being addressed.

Step 2 - Identify Resource Requirements

The answers to the questions above outline the requirements for the activity, which must include the requirements for quality. Once the basic requirements are established, you have to answer additional questions that will drive the implementation phase of the project. These questions include:

- What activities must be performed?
- What staff members are needed to complete these activities? Are these staff available? If not, what other options exist (e.g., will staffing limitations dictate achievable project quality or project design?)
- What resources and materials are needed to complete project activities? Are these resources/materials available? If not, what other options exist (e.g., will resource limitations dictate achievable project quality or project design)?
- If data are required, what kind of data are needed, how will they be collected, and what are the quality requirements?
- Can we achieve these requirements within the schedule, using the available technical, financial, and staffing resources?

If you do not have suitable answers to these questions, then you may need to modify the design or scope of the activity to ensure that the product will meet the quality requirements on schedule and with the available resources.

Step 3 - Identify Performance Measures

The third step is to identify how you will recognize if you have been successful. As in:

- How can we measure the success of the project (e.g., through quantitative measures, surveys, peer review, etc.)?

The measure of success is an important aspect of the assessment and corrective action phases of the project, which are discussed at the end of this chapter.

Planning Tools

The Office of Water approves the use of a variety of planning tools that can help you manage the quality of your activities. These tools include quality and peer reviews, the use of simple software tools that may be used to identify project milestones and resources, and a formal multi-step process used to derive qualitative and quantitative statements concerning data quality objectives for the project. Possible planning tools are described below. This list is not exhaustive, and Office of Water staff are free to use any other tools that may facilitate their planning processes. The selection of appropriate planning tools should be done on a case-by-case basis using the graded approach described in this quality management plan. In accordance with the Office of Water's bottom-up philosophy concerning implementation of the

quality system, the selection of appropriate planning tools should be made at the lowest possible level (i.e., the project or Branch level).

Quality Review: Also known as peer input or peer consultation, this type of planning review refers to the involvement of technically qualified peers during the development of an Agency work product and includes an open exchange of data, insights, and ideas. Depending on the project size and scope, it may be advisable to ensure that stakeholder concerns are represented in this review.

Note: In accordance with EPA's Peer Review Policy, peers or stakeholders who provide active, ongoing input and participation in the development of a work product are not eligible to undertake a formal peer review of that work product because they lack independence from its development.

Checklists: Certain projects may be small enough, routine enough, or straightforward enough that quality can be adequately planned through the use of standardized checklists developed at the Office, Division, Branch, or even Project level. For example, the EPA Quality Staff recently published draft guidance on using data from other sources, e.g., secondary uses of data. This draft document dated May 25, 2001, and entitled *Using Data from Other Sources — A Checklist for Quality Concerns* is available on the Quality Staff web site (www.epa.gov/quality). The Office of Water encourages each program office to consider the development and use of checklists to facilitate efficient planning and documentation of such projects.

Project Scheduling Software: Commercially-available software designed to identify project milestones including interim deadlines, identify resources needed to complete the project, and identify scheduling conflicts. These tools typically allow projects to be either forward-scheduled (i.e., planned forward from a specific project start date) or reverse-scheduled (i.e., planned backwards from the scheduled project due date).

Data Quality Objective Process: A formal, multi-step process described in EPA's *Guidance for the Data Quality Objective Process (G-4), August 2000, EPA/600/R-96/05* as a systematic planning tool for environmental data collection. The process was originally developed around primary data collection activities and while it may be applicable to establishing objectives for secondary uses of data, it retains a focus on primary data collection. Therefore, although it is not required, **the Office of Water highly recommends that it be employed where practical.**

Formal Peer Review: EPA has a formal Peer Review Policy, described in the EPA Peer Review Handbook. In accordance with this policy, **the Office of Water requires that Peer Review be incorporated into the planning process for *all major, scientific or technical work products.*** This documented, critical review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the major scientific or technical work product and of the documentation that supports this product. The determination that a scientific or technical product is "major" is based on whether it meets at least one of the following criteria:

- Does it support major regulatory decisions or policy/guidance of major effect?
- Does it establish a significant precedent, model or methodology?
- Does it address controversial issues?
- Does it focus on significant emerging issues?
- Does it have significant cross-Agency/inter-Agency implications?
- Does it involve a significant investment of Agency resources?
- Does it consider an innovative approach for a previously defined problem/process/methodology?
- Does it satisfy a statutory or other legal mandate for peer review?

If your project meets one or more of the above criteria, you must consult the Peer Review Handbook to determine if the formal peer review process is required and to identify appropriate planning

measures that need to be taken to ensure that project schedules and resources are adequate to allow for this review.

Whatever planning tools are employed, they must be used in a systematic fashion. A graded approach to planning ensures that the level of detail addressed in the planning phase is commensurate with the importance of the work, its intended use, the available resources, and the schedule.

Implementing Quality Management Activities

As described in Chapter 3, all Office of Water staff and managers are responsible for implementing this quality management plan. The Assistant Administrator, Office Directors, Division Directors, and Branch Chiefs do so by committing the staff, training, and other resources necessary to successfully implement the quality management at the project level. The Quality Assurance Manager, Quality Assurance Officers, and Quality Assurance Coordinators implement this plan by:

- Assisting project managers and staff with incorporating quality management into their daily activities,
- Monitoring program activities to ensure that the quality system is being implemented as planned, and
- Reporting the status of quality management activities to senior management and EPA Quality Staff

Implementation of quality management activities at the project level depends on the specific activities involved in the project. As a result, it is not practical to suggest a cook book approach that will cover all projects. However, the staff participating in a project can start to implement the quality system by meeting the following generic requirements:

- Make sure you are aware of and familiar with any approved quality assurance project plans or other documents governing the quality system to be used on the project. Project managers must provide this information to the technical staff. If the staff have not received such materials, then they need to ask the project manager if they exist.
- Identify your specific responsibilities listed within these materials. If such materials do not exist, identify specific steps you can take to ensure the quality of work you produce.
- Consult with the project manager and/or technical peers about changes in project scope or unanticipated problems that may not be adequately addressed by the existing quality system.
- Document problems that you encounter on your project, including any deviations from the quality assurance project plan or other quality system documentation, and the steps taken to resolve those problems. (Documentation requirements are described in greater detail in Chapter 5).

Evaluating the Results and Making Adjustments

The planning and implementation aspects of quality management are not performed simply to satisfy the requirements of the EPA quality order. Rather, they are the first steps in the quality management process. It is not possible to manage quality or learn from past mistakes without evaluating the results of a project in relation to the plan and taking any corrective actions that may be needed. Closing the quality cycle requires evaluating the success of the project and considering how the process can be improved.

There is a wide range of tools and processes available to evaluate the quality of these activities and their resulting work products. The Office of Water encourages the use of any processes or tools that promote cost-effective quality assessments and recommends that these tools be selected at the project or Branch level.

The ultimate goal of any given evaluation is to determine which aspects of the quality system are working properly and which are not. However, the common perception of any of these evaluations is that they are designed simply to find problems. That perception can lead to an "us versus them" mentality that

pits the evaluators against the staff performing the work and defeats much of the purpose of the quality system. Everyone in the Office of Water has a responsibility to make the quality system work effectively.

Several of the evaluation tools are the same as those used to plan quality management activities. For example, peer consultation and peer review are effective ways to obtain an independent assessment of the quality of data generated in the project, or of the final work product. Similarly, project managers can use project scheduling software to compare the original project schedules and resource estimates against the final schedules and resource utilizations. The point of the evaluation is not to cast blame for delays or other problems, but rather, to identify aspects of the project that posed problems and build on that knowledge when designing future projects.

Other tools are specifically designed to facilitate the evaluation phase of the quality system. These include data validation, data quality assessment, technical system reviews or audits, management system reviews, annual program reviews, and quality system audits. The evaluations described below, along with recommended corrective strategies, may be carried out internally, by staff from the Office of Water, by contractors under the direction of Office of Water staff , or by external parties, including the EPA Quality Staff.

Internal Peer Consultation

Consulting with one's peers is a useful and important form of evaluation. It is also one that many people practice already without giving it much thought. The process can range from an informal request for a coworker to "take a look at this for me" to a more formal review. Peer consultation may go by other names as well, including a "quality review" in some organizations. However, it should not be confused with the formal "peer review" process established at EPA.

This form of review can apply to both technical and non-technical products, including correspondence. Peers can provide needed editorial reviews, but they can also help identify other weaknesses in work products. The scope and value of the review will depend on the reviewer's knowledge of the subject matter and their own skills. Thus, if the goal is an editorial review, the reviewer should be a good writer or editor. If the goal is an evaluation of the technical merits, then the reviewer should have a firm grasp of the technical aspects of the material.

The Office of Water quality system encourages the use of peer consultation, but does not require it as a formal process. However, whenever a peer is consulted, the comments from that consultation should be maintained as a record of the consultation itself. This could be as simple as retaining a marked copy of the product containing the reviewers comments, along with the reviewer's name and the date of the consultation. Comments in an electronic form may serve the same purpose, provided that they can be traced to the reviewer and the date.

Responses to Peer Consultation: As noted earlier, peer consultation is a useful, but not necessarily formal, process. Therefore, no set responses are described here. However, common sense applies. Obviously, typographical errors must be addressed and editorial comments should be considered in revising the product. When major technical issues are identified, the reviewer and the developer or author of the product should work together to determine if the issues are symptoms of a systematic problem. Where needed, line management and the relevant quality system staff should be brought into the process.

Formal Peer Review

Peer review is a formal Agency process that uses technically qualified peers (persons of equal or greater skill to your own) to ensure independently the quality of all major, technical work products. It is an essential Agency requirement covering the review of technical products and the *scientific and technical* aspects of *major* products, and it is described earlier in this Chapter.

The Assistant Administrator is the ultimate decision maker and is accountable for implementing the Peer Review Policy within the Office of Water. The Assistant Administrator may designate Office directors and Division Directors or other appropriate level line-managers as the front line decision makers.

Responses to Formal Peer Review: By its very nature, the peer review process is a formal one. In general, every peer review comment must be formally addressed. Some comments may be addressed by incorporating them or making the suggested changes, other comments may be addressed by careful rebuttal, or by demonstrating that they are not relevant. The response to the peer review comments must be documented in accordance with the peer review policy.

Data Validation

As used in this quality management plan, data validation refers to an evaluation that is applied to primary data collected under EPA's direction. The goal of data validation is to ensure that individual results collected to support an EPA decision are valid in the context of the manner in which they were collected. For sampling and analysis activities, "valid" data can be traced from the collection of a given sample in the field, through the procedures employed by the laboratory performing the analysis, to a final report of the results. Validation also examines the issue of "completeness" of a data set by determining if results were produced for every sample that was collected, and if not, why not.

Data validation also involves a comparison of the sampling and analysis data against the acceptance or performance criteria for the data. The criteria may be the result of the data quality objectives process, but often are derived from the performance specifications of the sampling and analysis methods employed for the specific project. For example, data validation may involve the examination of the quality control data for various types of blanks, calibrations, and spiked sample analyses that are called for in many EPA analytical methods, relative to the performance specifications in those methods. Validation also may involve the comparison of the actual sample collection procedures with the sampling design described in the planning documentation to determine the likelihood that the materials collected accurately represent the source. The results of these evaluations may include a determination that the data meet the criteria, that they do not meet the criteria because of poor performance by the samplers or the laboratory, or that they do not meet the criteria because of problems inherent in the samples themselves.

Within the Office of Water, data validation activities are most likely to be employed for field sampling and analysis projects, such as effluent guideline development studies. Because these activities involve standardized methods for sampling and analysis, data validation is generally performed in accordance with a standard operating procedure that is specific to the analytical methodology.

Responses to Data Validation: Data validation typically identifies two distinct types of problems - those associated with poor laboratory performance, and those associated with factors outside of the laboratory's control, including problems related to the sample matrix itself or problems related to the sample collection and shipping processes. Whatever the source of the problem, the goal of data validation is to obtain data that meet the quality required for the specific project and to identify when that goal has not been met.

When the results of data validation efforts identify problems with laboratory performance, several forms of corrective action may apply. For example, the laboratory may be required to reanalyze individual samples associated with the performance problems at no additional cost to EPA. For problems that indicate a more pervasive failure of the laboratory's quality system, it may be appropriate to negotiate a more systematic solution to the problem, including changes in the laboratory's internal quality system. In extreme cases, it may be necessary to take formal contract action against the laboratory. In this latter instance, the response may not change the quality of the data already generated for the specific samples or the project, rather, it may prevent future data quality problems.

In contrast, the validation process may identify problems that are outside of the control of the laboratory, including when the requested methods apply to the samples less than ideally, or problems associated with the collection or shipment of the samples themselves. In these instances, it is critical that EPA and the laboratory work together to determine the source of the problems so that EPA can take corrective actions. In some cases, part of the corrective action is to ensure that the data users understand the limitations of the quality of the data that were produced, so that they can adjust their use of the data or their conclusions about their meaning. Other cases may also involve corrective actions by the party collecting and shipping the samples.

Data Verification

As noted in Chapter 2, the Office of Water may make secondary use of data from other sources in making environmental decisions. The data may take a variety of forms, ranging from primary data generated by others with all the commensurate supporting information, to data compiled from literature sources, to the results of modeling efforts, or even to data drawn from anecdotal sources. Whatever the original source of the data, the Office of Water requires that reasonable efforts be made to verify the data and to assess their quality to the greatest extent possible.

In the context of this plan, data verification refers to all efforts to determine if the data are properly represented. This may include going back to the original published source of the information, rather than relying on a summary or a citation in a review article. It may involve contacting the person who provided the data and confirming the specific manner in which they were generated. If the data are the result of a modeling effort, then the model should be examined to ensure that the results were generated as intended. If the data involve calculations of descriptive statistics and the original data are available, then the calculations may be spot-checked for accuracy. Where the data are primary data from some other source, it may be possible to perform data validation procedures such as those described above. If the Office of Water did not control the generation of those data, then it may not be possible to effect any corrective actions to improve the quality of the results. **Nevertheless, it is critical that the quality of the data be known to the greatest extent possible and that any limitations to the use of the data be identified and documented.**

Data Quality Assessment

A data quality assessment is a formal scientific and statistical evaluation to determine if the data obtained from an environmental data operation are of the right type, quality, and quantity to support their intended use. The need to conduct a data quality assessment is a project-specific decision and will be specified in project-level quality system documents such as a quality assurance project plan.

The most current version of *Guidance for Data Quality Assessment: Practical Methods for Data Analysis*, EPA QA/G-9, may be used to assist in the data quality assessment process. Data quality assessments are the responsibility of the project managers and the level of effort for the data quality assessment should be commensurate with the project objectives and intended use of the data.

Data quality assessments often are conducted during and/or at the end of the data collection activity. They may be performed during the project if the project manager has identified concerns about data quality. The project manager, with assistance from the quality assurance officer is responsible for determining the need for a data quality assessment. The process provides the necessary steps for the statistical analysis of data to determine whether or not the data meet the objectives of the project and with what level of confidence these data may be used. The result of a data quality assessment is a quantitative statement of the limitations on the quality and potential uses of the data. If deficiencies are found, potential technical and managerial causes are examined, and follow-up measures identified.

The results of the data quality assessment will be documented and provided to the Project Manager. The Project Manager is responsible for reviewing the results, determining any corrective actions that are needed, and confirming the implementation and effectiveness of those corrective actions.

Responses to Data Quality Assessments: Data quality assessments conducted during the project afford an opportunity for ongoing corrective action. Data quality assessments conducted at the end of a project provide a means of verifying the utility of the data, the need for a new project effort, or determination of the feasibility of a long-term program.

The response to a data quality assessment may be to revise the systematic planning process for future activities to avoid the data quality problems that were identified in the current projects. The response for a specific project could include modifying the decision to match the quality of the data, or to collect more data.

Technical System Reviews or Audits

A technical systems review or audit is also known as a field and laboratory audit. It focuses on the actual environmental measurement data collection systems, documentation, and the quality control data associated with those systems.

A technical systems audit is a thorough, systematic, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of field and laboratory activities. A technical systems audit often entails a site visit and an examination of sampling and measurement procedures, personnel training, general laboratory cleanliness, support systems, equipment and facilities, calibration, maintenance, and repair records, control charts, etc. However, other approaches may be employed, including the use of performance evaluation samples relevant to the project.

Given the costs associated with technical systems audits, it is not practical to conduct them for every data collection project. Moreover, since much of the sampling and analysis performed for the Office of Water is conducted by a small number of contractors with multi-year contracts and operating across a variety of projects, it may be more practical to rely on the results of routine pre-award and post-award audits of these contractors then to conduct project-specific reviews for every project. The frequency of such audits should be based on the schedule for the project and the length of the contract.

Thus, under the graded approach, technical systems audits may be reserved for specific projects, based on the importance of the project, the risk of a decision error, the schedule for completion, and the available resources. The need for a technical system audit should be established and documented during the initial planning phase of the project.

The most current version of the document *Guidance on Technical Audits and Related Assessments,* EPA QA/G-7, may be used to plan and conduct an audit, with modifications appropriate for the types of data that are being collected. Technical systems audits may be facilitated by the use of checklists geared to the types of activities and analyses involved in the project. However, the auditors must be competent scientists who are familiar with the particular data collection technology and procedures. Therefore, the auditors will be selected on the basis of their demonstrated skills. Audits of field operations may require staff with different background and expertise than those who conduct laboratory audits. Where there are project-specific concerns or anticipated problems, the project manager must provide that information to the auditors.

Audits will be scheduled and tracked by the Quality Assurance Officer in consultation with the project manager. The roles, responsibilities, and independence of the evaluation personnel, the process for reviewing, reporting and responding to corrective actions, and the process for ensuring the implementation and effectiveness of corrective actions can vary among projects. Therefore, these details

will be defined in a plan specific for each audit. The results of technical systems audit are provided to the appropriate line and program supervisors.

Responses to Technical Systems Audits: The results of a technical systems audit may point to pervasive problems that go beyond the results for a small number of the samples. As a result, the responses need to be on a similar scale. If a pre-award audit finds significant problems, then the EPA project manager must choose an appropriate response that is based on the project schedule. This could include finding another contractor, improving communications between EPA and the contractor, or an intensive effort by EPA to work with the contractor to resolve the problems now in order to meet the project deadlines.

The responses to the findings of an audit conducted during the course of a project should be designed to maximize the quality and quantity of the data to be delivered to EPA.

Quality System Audits

Quality system audits were previously called management system reviews. The new term was adopted by the EPA Quality Staff in response to new protocols from the Government Accounting Office and the change was designed to clarify that it is a review of the quality management system, and not other types of management systems. Quality system audits evaluate a specific quality system associated with environmental data collection activities to either affirm the correctness and appropriateness of the quality system approach or to identify areas where additional attention would bring significant benefits. There are two types of quality system audits: internal and external. Internal quality system audits may be conducted at the level of a given Program Office, or as an internal review of the Office of Water quality system itself. External quality system audits may be conducted by EPA's Quality Staff to determine the compliance of Office of Water Programs with the quality management plan. EPA's Quality Staff web site provides resources and guidance to assist in Quality System Audits.

The Quality Assurance Manager, with assistance from the Quality Assurance Officers and senior Office of Water management, will select Office of Water programs for internal quality system audits. Given that this is a five-year quality management plan and there are five program offices, this equates to one program per year. The audit will be performed by Quality Assurance Officers from the other Program Offices within the Office of Water, with assistance from a technical team selected by the designated lead quality assurance officer and approved by senior Office of Water management. The Office of Water will initiate the internal quality system audit process one year after approval of the new quality management plan.

An audit of the Office of Water's quality system assesses the quality management structure, the quality management plan, and other office-wide quality system components, to determine whether Office of Water is implementing a satisfactory quality system. During the audit, the effectiveness of, and adherence to, the approved quality management plan, as well as the adequacy of resources and personnel provided to implement the quality system will be evaluated by the audit team.

The following issues are examined during both internal and external quality system audits:

- Adherence to the Office of Water quality management plan
- Procedures for developing data quality objectives and other acceptance criteria
- Procedures for developing and approving quality assurance project plans
- Quality of existing quality assurance project plan guidance and quality assurance project plans, e.g., is the guidance effective and do the plans meet the EPA requirements?
- Procedures for developing and approving standard operating procedures
- Procedures, criteria, and schedules for designing and conducting audits
- Tracking systems for ensuring that the quality system is operating and that corrective actions disclosed by audits have been taken
- Degree of management support

- Responsibilities and authorities of the various line managers and the quality assurance officer for carrying out the quality system
- The level of financial resources and personnel devoted to implementing the quality system
- Existence of appropriate quality system documentation and its conformance with the requirements of the quality management plan

The Office of Water Quality Assurance Manager will assist the audit team in determining the scope of the internal audit, planning, scheduling and implementing the audit. The findings are presented to the Assistant Administrator for Water and the Office of Water Office Directors. The results will appear in a findings report. Information on the results of the quality system audits will also be included in the Quality Assurance Annual Report and Work Plan.

The Office of Environmental Information Quality Staff implement independent quality system audits of the Office of Water quality system once every three years. Usually, the review team includes individuals from the Quality Staff, from other EPA Offices, or Regions who spend a week at the Office of Water meeting with management, interviewing staff, and performing file reviews. The audit results are reported to the Office through a draft findings report.

Responses to Internal and External Quality Systems Reviews: Senior management is responsible for determining necessary actions and developing a plan to address weaknesses disclosed in both internal and external quality system audits. For internal audits, milestones must be developed so that progress on corrective actions can be measured. Managers are responsible for ensuring compliance with the approved corrective actions. Progress is to be reported to the Administrator, Division and Office Directors, and the Federal Managers' Financial Integrity Act Coordinator. This will include identifying any problems in audits discussing corrective actions and summarizing follow-ups on the previous year's agenda. If major deficiencies are found, follow-up audits may be required and should be discussed with senior management. The Quality Assurance Annual Report and Work Plan will summarize the results of, and response to, any internal quality system audit conducted during the previous fiscal year.

For external quality system audits, the Office of Water must respond to the results of the audit and develop a corrective action plan to address any issues which require corrective action. The roles and responsibilities of auditors, experience and training for audit personnel, independence of audit personnel, and headquarters' management review of and response to findings for quality system audits are established by the Quality Staff and are beyond the scope of this quality management plan. The Quality Assurance Annual Report and Work Plan will summarize the results of, and response to, any quality system audit conducted by the Quality Staff during the previous fiscal year.

Annual Program Review

Each year, the Office of Water is required to submit a Quality Assurance Annual Report and Work Plan that summarizes the quality management activities conducted during the preceding year in all parts of the Office of Water. It also reports on all reviews and audits conducted during the year, any actions taken in response to those reviews, and plans for activities in the coming year.

As part of the process of preparing the annual report, all programs involved in the collection of environmentally-related data will review their quality system documents to determine if they remain relevant to the mission of the program and if they ensure that data of known and sufficient quality are used to support programmatic decisions. Ensuring that this review occurs is the responsibility of Branch Chiefs and/or Division Directors responsible for implementing the program, with assistance from the respective Quality Assurance Coordinators and Quality Assurance Officers.

At least annually, Office of Water management will meet with the Quality Assurance Manager, Quality Assurance Officers, and Quality Assurance Coordinators to discuss adherence to the quality

system and to identify areas where improvements can be made. Corrective actions will be developed to correct any major deficiencies and outlined in the annual report and work plan.

Dispute Resolution

Disputes involving evaluations are not uncommon. Such disputes will be addressed at the lowest level of management that is practical, as described in Chapter 3 of this quality management plan.

Quality Improvement

One goal of this quality system is to afford all Office of Water programs with opportunities to improve the quality of their products, including decisions based on environmental data.

Office of Water staff at all levels are accountable for continuous quality improvement. The process of continuous quality improvement leads to a better and more responsive quality system. The supervisors, project managers, and other technical staff have the most direct experience with the quality system process and are encouraged to identify opportunities for improving the quality system by contacting the Quality Assurance Manager directly or through discussion with their management or Quality Assurance Coordinator.

In an effort to encourage an open dialogue regarding quality system improvement, and to help staff perform their jobs, the team performing a quality system audit will often ask questions about the support received by personnel from the Quality Assurance Officers and Quality Assurance Coordinators. The Quality Assurance Manager will also periodically meet with the Quality Assurance Officers and Quality Assurance Coordinators to discuss and address quality issues.

Chapter 5
Planning Documentation

Another critical aspect of the Office of Water's quality system is that the planning process must be documented. The three planning steps outlined in Chapter 4 result in various decisions that will guide the implementation of an activity. Those decisions form the basis of a "plan" for the activity and that plan is a quality system document.

If you did not write it down, then it did not happen.

Quality system documentation can take a variety of forms. Two of the most common forms are a quality management plan such as this one, and a quality assurance project plan for an activity involving the collection of environmental data. The reference section of this document contains the titles of the latest guidance and requirements documents for those plans that are available from the EPA Quality Staff. These plans do not apply to every decision-making activity that may be conducted within the Office of Water, and may apply poorly to others. Therefore, the Office of Water's quality system explicitly recognizes that there are other formats in which the systematic planning of activities can be documented and that **content is more important than format.**

The questions asked in the planning process and the answers that result *must* be documented in writing in some fashion. Applying the graded approach, the format could be a checklist of questions and answers, a simple "white paper" outlining the planning decisions, or more detailed, formal, quality assurance project plan. One of the issues to be addressed during the planning phase of an activity may be the nature of the quality system documentation that will be employed. **Attachment A is a checklist for quality system documentation that may be employed to document the planning process.** The checklist is provided as guide and is not intended to limit or hinder the use of other documentation.

According to the *EPA Quality Manual for Environmental Programs*, the eight elements of the planning process listed in **Exhibit 6** must be documented. The specific details of these elements are addressed in the three suggested planning steps described in Chapter 4. Whatever form of documentation is used, it must address these elements of the planning process.

Exhibit 6
Eight Elements of the Planning Process That Must Be Documented

1. Identifying the project manager, the sponsoring organization and the responsible individual within that organization, the project personnel, the "customers" and "suppliers," and describing their involvement in the project.
2. The project goal, objectives, and the questions and issues to be addressed
3. The project schedule, resources and budget, and milestones, and any applicable requirements (e.g, regulatory or contractual requirements)
4. The type of data needed and how those data will be used to support the project objectives
5. How the quantity of data needed was determined and how the criteria for the quality of the data were determined
6. How, when, and from where data will be obtained, including existing data. Identifying any constraints on the data collection process
7. Specification of the activities during data collection that will provide the information used to assess data quality (i.e., field or laboratory quality control operations, audits, technical assessments)
8. How the data for the project will be analyzed, evaluated, and assessed against their intended use and the performance criteria established above.

Quality Assurance Project Plans

A commonly-used form of documentation for primary data collection activities is the quality assurance project plan. A quality assurance project plan is a technical planning document that defines the objectives of a project or continuing operation, as well as the methods, organization, and quality management activities necessary to meet the goals of that project or operation. It serves as the blueprint for implementing the data collecting activity, to ensure that the technical and quality goals of the operation are met. It also provides the necessary link between the required data quality constraints and the sampling and analysis activities to be conducted. The quality assurance project plan must be approved by the management and quality system staff of the organization conducting the project (e.g., the Project Manager, Branch Chief, and Quality Assurance Coordinator) prior to any data gathering or use, as described below. In some cases, the format of a quality assurance project plan can be adapted to describe the collection of data for secondary use.

Equivalent Documentation

EPA Order 5360.1 A2 requires that the quality system require quality assurance project plans or "equivalent documents" for all projects and tasks involving environmental data. Such documents must be approved by the management and quality system staff of the organization conducting the project (e.g., the Project Manager, Branch Chief, and Quality Assurance Coordinator) prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

The allowance for "equivalent documents" is critical to successful planning and documentation of many activities covered by this quality management plan. For example, the Office of Water funds a variety of grants to States, Tribes, and public and private organizations that advance the overall mission of the Office. Some of those grants involve the collection of environmental data, but are for small dollar amounts that simply cannot support the production of elaborate quality system documents such as quality assurance project plans. Other grants may involve the collection of environmental data that are never going to be used to make an environmental decision, but rather are used as a means to raise public awareness of environmental issues or provide educational outreach. Therefore, these data collection activities need not be documented in a format as formal as a quality assurance project plan. In addition, the EPA Order now addresses the secondary uses of data, as described in Chapter 2, whereas the traditional quality assurance project plan requirements are clearly designed to address primary data collection activities and may not adequately address secondary data.

Therefore, the **Office of Water quality system explicitly provides for a graded approach to the documentation of environmental data collection activities.** The most stringent approach to such documentation remains a quality assurance project plan. As part of the planning process, project managers may decide to specify that another form of documentation will be employed.

Documentation for Primary Data Collection

Unless the planning process specifically identifies a rationale whereby it is not necessary, a quality assurance project plan will be prepared for all primary data collection activities by EPA or at EPA's direction by contractors. The quality assurance project plan will conform to the basic format outlined in the most recent Quality Staff requirement documents available at the time the plan is prepared (e.g., QA/R-5, see reference section). When identified during the planning stages, such quality assurance project plans may be written at the broadest possible level, e.g., covering data collection across related sites for a given project, and supported by additional documents that are site-specific, or address additional details not covered in the quality assurance project plan.

The quality assurance project plan must be approved and in place prior to the start of data generation or use. It is the responsibility of the Project Manager to ensure an approved quality assurance

project plan is in place prior to the start of data generation or use. **A generic checklist for reviewing quality assurance project plans is included in Attachment B.** It outlines 24 elements of a quality assurance project plan and asks questions about how the plan addresses various aspects of each element. This checklist may be used as is, noting those aspects and elements that do not apply to a given environmental data collection project, the checklist may be modified for project-specific needs, or another approach to reviewing quality assurance project plans maybe employed, so long as that approach and the results of the review process are documented.

For projects or tasks involving environmental data performed through grants and cooperative agreements (40 CFR Parts 30, 31, and 35), the planning process *must* identify the appropriate level of quality system documentation that will be employed. That decision may employ the graded approach described throughout this quality management plan. However, regardless of the approach chosen, the documentation must be reviewed and approved by the relevant Office of Water management and quality system staff prior to the start of data generation or use.

Documentation for Secondary Data Collection and Use

For projects that employ data from other sources (i.e., secondary data), the level of quality system documentation should be commensurate with the nature of the data and the decision to be made. EPA's ability to assess the quality of the results may vary. For example:

- Data may be primary data from another project. It may be possible to perform a detailed assessment of the data relative to the current use. In this instance, the quality system documentation could be written in a form very similar to a quality assurance project plan, with less focus on controlling of the generation of the data, and more focus on the assessment relative to the current use.

- Data may be collected from various sources in the literature and the underlying results may not be available in any form. In this instance, the quality system documentation could be in any format that outlines the steps that EPA will take to assess the results. That assessment might focus on obtaining copies of the original publications rather than relying on review articles. It could describe the process that EPA will use to compile and compare data from various sources, to ensure consistent units of measurement are used, etc.

- Data may be presented to EPA from some outside source as a *fait accompli*, e.g., the results of an industry-sponsored survey. The quality system documentation could focus on EPA's activities to assess how the data were collected, to verify the responses with the original sources, etc.

Whatever format is used for the quality system documentation, it should address the eight elements listed in Exhibit 6. The documentation must clearly identify all the instances in which the quality of the data cannot be controlled or assessed.

The Office of Environmental Information is developing guidance on using data from other sources. When the guidance is finalized, the Office of Water will review it and, if appropriate, incorporate the guidance into the procedures for assessing the quality of secondary data. In the meantime, the Office of Water will continue to use the planning process described in this plan to identify when secondary data will be used, to establish acceptance criteria for the data, and to outline the manner and extent to which secondary data will be verified. The project staff will continue to employ professional judgement to ensure that the data meet the needs of the project.

Documentation for Contracts, Grants, and Assistance Agreements

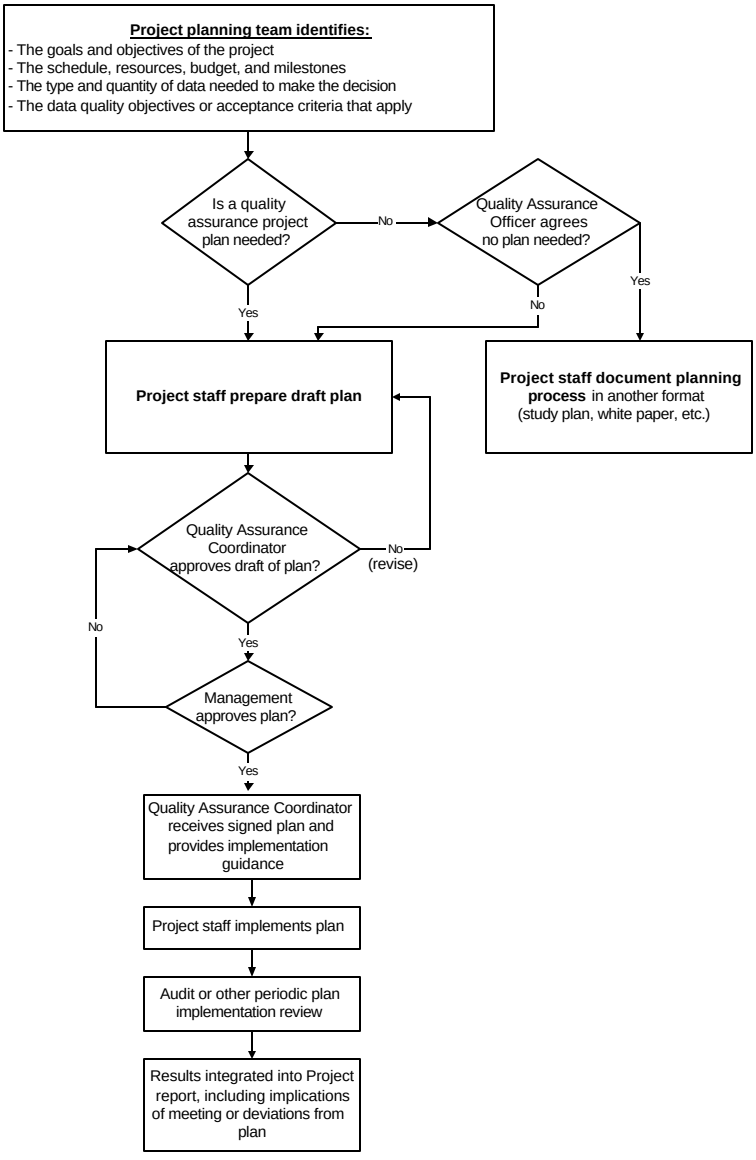
Chapter 9 describes how the Office of Water will incorporate quality system requirements into procurements and financial assistance agreements, including contracts, grants, assistance agreements, performance partnership agreements, and interagency agreements that involve the collection or use of

environmental data. The documentation associated with contracts, grants, and assistance agreements often is derived from other organizations within EPA, including the Office of Acquisitions Management. Attachments C, D, and E contain forms and checklists that are used to document activities associated with contracts, grants, and assistance agreements. The manager with responsibility for the contract, grant, or agreement and the corresponding member of the quality system staff are responsible for completing these forms and checklists, as well as complying with all other procurement or assistance requirements.

Preparation and Approval of Quality System Documentation

The Branch Chief has the ultimate responsibility for ensuring that the appropriate quality system documentation is prepared and approved for any project within the Branch. In general, the quality system documentation should be prepared by staff involved in the planning process. The project staff should prepare a draft of the quality system documentation that incorporates the decisions about data quality and assessment that resulted from the planning phase of the project. The general process for preparing and implementing a quality assurance project plan is shown in **Exhibit 7**.

Exhibit 7
Preparation and Approval of Quality Assurance Project Plans



This process also addresses the use of equivalent forms of quality system documentation. As part of the planning phase of the project, the team must decide what form of quality system documentation is most appropriate for the data collection activities. As noted elsewhere, the structure of a quality assurance project plan is built around the generation of primary data using field and laboratory procedures and it is a well-established and effective means in which to document those activities. However, the project team may wish to employ another form of quality system documentation for other types of data gathering activities, including those involving secondary uses of data, where the scope of the project does not warrant a quality assurance project plan (e.g., a small grant), or where the data collection activities are not directly associated with a decision by the Office of Water (e.g., educational activities or other outreach projects).

If the project team decides that a quality assurance project plan is not required, then that decision is presented to the Quality Assurance Officer for concurrence. The Quality Assurance Officer will consult with the Quality Assurance Coordinator for the project and notify the Project Manager of the decision. The project team will proceed accordingly and prepare the appropriate quality system documentation.

The draft quality assurance project plan is reviewed by the Quality Assurance Coordinator for the project. If the Quality Assurance Coordinator played an active role in preparing the plan, then to ensure some level of independence, a Quality Assurance Coordinator from another Branch should perform the review. In addition, depending on the nature of the project, it may be reviewed by the Quality Assurance Officer and management in the relevant program office (the need for such higher level reviews should be identified during the planning process). As needed, it is returned to the project staff for revisions. Once approved by the Quality Assurance Coordinator, it is sent to the Branch Chief for review. Issues identified during the review by management should be addressed by the quality system staff, with input where needed from the project staff. Final approval of the document is indicated by the signatures of the project's technical leader, the Branch Chief, and the Quality Assurance Coordinator. Where the planning process identifies the need for review and approval by higher levels of management, the documentation will be submitted to the Quality Assurance Officer and the Division Director as well. For projects involving contractors and particularly sampling and/or laboratory contractors, the quality assurance project plan must be reviewed and approved by the contractor's management and quality system personnel as well, since they are going to be bound by the constraints of the plan.

Contractors and grantees may prepare quality assurance project plans for the projects in which they are involved and may also provide support to EPA in preparing quality assurance project plans for use by others. However, the essential planning steps, including establishing the data quality objectives and/or the acceptance or performance criteria, must be carried out by EPA. In other words, if EPA is making the environmental decision, then **EPA decides the quality of the data needed to support that decision.**

Standard Operating Procedures

Procedures that are routinely employed by staff in the Office of Water in the collection, evaluation, or use of environmental data within a program or project may be formalized as a standard operating procedure. The decision to prepare a standard operating procedure will depend on the nature of the procedure, the schedule for the completion of the project, and the available resources. The format of the standard operating procedure will be determined by the Project Manager, in consultation with the technical staff and the Quality Assurance Coordinator. Standard operating procedures will be reviewed by the Project Manager, the Branch Chief or other appropriate manager, and the Quality Assurance Coordinator. Once approved, each procedure will have a unique title, a revision number (starting with 0 for the original issue), and the date of issue. The Project Manager will distribute standard operating procedures to the appropriate staff and ensure that any superceded procedures are removed from circulation and use.

Chapter 6
Management of Quality System Documentation and Records

As noted throughout this plan, the Office of Water quality system is designed to be an integral part of all activities within the Office. As a result, with a few exceptions, the documentation and records developed for the quality system are also an integral part of those activities. Therefore, to the greatest extent possible, **this plan advocates the integration of quality system documents and records into the systems used to manage all other Office of Water records.** This integration not only avoids unnecessary duplication of records and saves paper, it minimizes the need to consult different sets of records during audits and reviews.

In addition, this plan recognizes the utility and increased use of electronic records of all kinds, including quality system records. Thus, the records management provisions of this plan apply equally to paper and electronic records.

Office-wide Records

All quality system documents that apply across the Office of Water, such as this quality management plan and the quality assurance annual report and work plan, will be managed under the direction of the Quality Assurance Manager.

In order to facilitate the widest possible distribution and use of these documents within the Office of Water, electronic versions of the documents will be posted on an internal Office of Water web site. There is no need for such office-wide documents to be issued in a "controlled" fashion, where each copy is uniquely numbered and tracked by the issuer. However, all Office-wide quality system documents will be dated on every page, for example, using headers or footers to indicate the month and year of issue, and include the revision number, beginning with revision "0" for the original issue. The Quality Assurance Manager will determine the appropriate electronic format in which to distribute the document, including as a WordPerfect document (WPD), or an Adobe portable document format (PDF).

Because the approval signatures on quality system documents are not easily incorporated into electronic formats, the electronic versions of the documents posted on the web site will not be signed. Rather, the signed originals or photocopies will be maintained by the Quality Assurance Manager as proof of the approval of the document. Signed photocopies may also be distributed to the signatories and others, as needed. The electronic versions may have text inserted on the signature page noting that the signature page is maintained on file and directing the reader to the Quality Assurance Manager.

When changes are made to Office-wide quality system documents, the revised documents would be posted on the web site and the earlier versions electronically archived and removed from the web site. A notice of the availability of the revised document will be routed to all staff in the Office of Water electronically, or in hard copy, as needed, by the Quality Assurance Manager. The revised document will be identifiable by the issue date and revision number, as described above.

Records of all evaluations of the quality system, such as internal an external quality system audits, technical system audits, and others, will be maintained by the Quality Assurance Manager. The format and distribution of these records will be determined by the Quality Assurance Manager, in consultation with senior management.

Program-specific Records

When a Program office within the Office of Water develops quality system documents, those documents will be managed by the Quality Assurance Officer for the program office, in a fashion similar to that described above for Office-wide documents.

Records of all evaluations of the Program-wide aspects of the quality system, such as quality system audits, technical system audits, and others, will be maintained by the Quality Assurance Officer in each Program office. The format and distribution of these records will be determined by the Quality Assurance Officer, in consultation with senior management and the Quality Assurance Manager.

The Quality Assurance Officer will review any standard operating procedures developed at the Office level annually to ensure that they are still needed and up to date. Such standard operating procedures will be revised as needed, and when revised, will be issued with a new date and revision number. The Quality Assurance Officer is responsible for notifying all staff within the office of the revision of the standard operating procedures and for issuing copies in an appropriate format to all affected staff.

Project-specific Records

The volume of quality system documents generated at the project level is much greater than that produced at the Office- or Program-level. Thus, the integration of the quality system documents with other project files will be most effective in reducing duplication and discrepancies between different sets of records.

All quality system documents produced during a project, including quality assurance project plans, the results from the systematic planning process (e.g., the checklist in Attachment A), and documentation of any reviews or evaluations of project efforts, will be maintained in the project files in either electronic or paper format. As with Office-wide documents with approval signatures, the Quality Assurance Coordinator overseeing the project will maintain the original hard copies of the signed documents, with photocopies or electronic documents provided to all signatories and the Quality Assurance Officer.

The Office of Water has a Records Officer and a network of records managers from all Program and staff offices who institute and maintain the Federal and Agency records management procedures. Project-specific quality system documents will be managed under this system, along with the other project records.

The Quality Assurance Coordinator will review any standard operating procedures developed at the project level annually to ensure that they are still needed and up to date. Those standard operating procedures will be revised as needed, and when revised, will be issued with a new date and revision number. The Quality Assurance Coordinator is responsible for notifying all appropriate staff within the Branch (or Division) of the revision of the standard operating procedure and for issuing copies in an appropriate format to all affected staff.

Confidentiality

Particularly at the project level, Office of Water staff may have access to information that is considered to be proprietary or confidential by one or more parties. Examples include proprietary or confidential business information (CBI) collected from a regulated entity, enforcement-sensitive information collected during the course of enforcement proceedings by EPA or the Department of Justice, and information from Tribes and States. There are specific statutory requirements and policies that govern the use and disclosure of such information that are beyond the scope of this quality management plan. The Office of Water requires that all such confidential records be maintained according to those requirements and policies.

Office of Water staff must be aware of the presence of confidential information in relation to quality system documentation. For example, some information that is normally included in a quality assurance project plan may include CBI relating to the industrial processes to be sampled. If such CBI is included in the quality assurance project plan, then the entire plan is subject to the statutory CBI

protections and may not be placed in files that are not approved for CBI, or handled by staff without CBI training. Similarly, the documentation of reviews and evaluations could contain CBI or other sensitive information that is not suitable for general distribution.

Therefore, in order to minimize the number of quality system documents that must be retained under special circumstances, project managers are encouraged to identify the likelihood that information collected during the project will require special handling during the up-front planning effort. In planning the quality management activities for the project, reasonable efforts should be made to segregate confidential or sensitive information in documents such as quality assurance project plans. For example, if confidential or sensitive information is essential to the plan, it may be more practical to include the information in a separate appendix or attachment. The sensitive portion is then maintained separately from the bulk of the plan. Here again, a graded approach should be employed to balance the need for the information in the quality system documentation against the resources required to protect confidentiality.

Chapter 7
Quality System Training

It is Office of Water policy to provide the quality system training necessary to ensure that all staff involved with the generation and use of environmental data understand and use the Office of Water's quality system. The following sections describe the Office of Water's quality system training program.

Office of Water's Quality System Training Program

Following approval of this quality management plan, all Office of Water staff will attend a training course developed to explain the fundamental components of the quality system documented in the plan. In addition, all staff who perform tasks related to the generation, management, and/or use of environmental data, including Project Managers, laboratory analysts, field personnel, and data processors, need to understand quality management procedures and principles, and will participate in training related to the generation of environmental data.

Supervisors are responsible for ensuring that staff have the qualifications to do their jobs, including those related to the quality system. Managers are responsible for discussing quality training needs with personnel involved in environmentally-related data-gathering activities during the mid-year and annual personnel performance evaluations. The Individual Development Plans of all Office of Water quality system staff, supervisors, and managers will include appropriate quality system training requirements and standards.

In addition, because line management is ultimately responsible for the quality of data, managers and supervisors also must receive the necessary training to ensure their understanding of the importance of the quality system, their responsibilities as managers of data collection activities, and specific Office of Water quality system policies and procedures.

Role of the Quality Assurance Manager

The Quality Assurance Manager is responsible for identifying annual training needs for the office, disseminating information regarding available training opportunities for staff and management, and arranging Office-wide quality system training, with guidance and assistance from the Office of Environmental Information Quality Staff. Specifically, the Quality Assurance Manager will ensure that the following are addressed:

- Supervisors have the introductory training and any in-depth training that is routinely offered
- Project managers and EPA personnel will have a minimum of 8 hours of quality system training
- Quality Assurance Managers, Officers and Coordinators will have a minimum of 24 hours of training. Any additional quality system training to perform specific duties such as auditing or trainer training, and any technical training which would facilitate the understanding of the Agency’s operations would be discussed in the individual’s mid-year and annual performance appraisal.
- The necessary training is made available to all grantees including State and Tribal personnel.
- All trained staff members take a refresher course every three years.
- Any special training requests by EPA, State, or Tribal personnel are coordinated.

The Quality Assurance Manager is responsible for arranging or providing for the training needs identified by the Divisions and Program Offices. Specific organizational training needs will be addressed annually in the Quality Assurance Annual Report and Work Plan.

Training Requirements

Quality system training requirements can be met by attending seminars developed by EPA Quality Staff or through equivalent in-house training. Quality Staff has made training materials available on the internet so that staff may use the materials to develop training courses to meet mission-specific needs.

The Office of Water's training program incorporates a graded approach relative to the functions performed by the various groups of personnel. This section outlines the minimum quality system training requirements for the various groups of personnel. These core courses may be modified to address specific program needs. Additional quality system training needs identified by the Divisions, Program Offices, and Quality Assurance Coordinators will be provided when needed.

Supervisors and Quality Assurance Coordinators, with necessary assistance from Quality Assurance Officers and the Quality Assurance Manager, are responsible for identifying and providing Program-specific quality system training. Minimally, supervisors will assess and summarize their needs annually, and will provide the listing to the Quality Assurance Coordinators for inclusion in the Quality Assurance Annual Report and Work Plan.

Exhibit 8
Training Requirements by Position

Position	QA Training Requirements
Managers (Branch Chiefs, Division Directors)	• Overview of the Office of Water quality system • Orientation to Quality Assurance for Managers and Supervisors
Supervisors	• Overview of the Office of Water quality system • Orientation to Quality Assurance for Managers and Supervisors
Work assignment managers, project managers, project officers, lab personnel, and field personnel	• Overview of the Office of Water quality system • Introduction to Quality Assurance Project Plans • Introduction to Data Quality Objectives
Office of Water quality system staff (QAM, QAOs, and QACs)	• Overview of the Office of Water quality system • Introduction to Quality Assurance Project Plans • Introduction to Data Quality Objectives
All Office of Water staff involved in the generation or use of environmental data	• Overview of the Office of Water quality system

Attendance at the courses will be recorded, and attendees will receive a written record from the Quality Assurance Manager or instructor after completion of a course. The Quality Assurance Officers will maintain records of the quality system training taken by personnel in each Program Office. A summary of the quality system training will be provided in the annual report, including, but not limited to, a list of the courses offered, the number of attendees, and a listing of all participating organizations.

Training for Grants and Contracts

Grant recipients or contract personnel involved with environmental data generation and use also must have the necessary quality system training to successfully complete their grant or contract tasks and functions. Project managers are responsible for ensuring that the quality system training requirements are described in the organization’s approved quality system documentation. Work assignment quality system requirements may be delineated in the Request for Proposal, the statement of work, and/or the work assignment. The Quality Assurance Manager will ensure that an overview of the quality system training course will be provided in addition to providing the financial assistance management and contract administration training courses.

Chapter 8
Information Systems

The Office of Water recognizes that the success of the national water program depends on information systems that meet the needs and quality standards of internal and external customers. The Office of Water has developed a variety of information systems ranging from general support systems and major applications with broad applicability across to the Office of Water to smaller, specialized, and often ad hoc, information systems that may include small databases, spreadsheets, and data entry tools that are used only by project staff. The graded approach to quality management also applies to all these information systems.

General Support Systems and Major Applications

The Office of Water ensures that general support systems and major applications meet customer needs and quality standards in three ways.

- Adhering to all Federal (laws, Presidential Decision Directives and Memorandums, and Office of Management and Budget guidance) and EPA standards pertaining to hardware, software, system development, and data. These standards can be found on the Office of Environmental Information page of the EPA Internet web site (http://www.epa.gov/oei/index.htm) under the *Policies* heading.

- Adhering to all EPA data standards to reduce confusion caused by multiple methods of representing the same information across EPA regulations, reporting requirements, and databases. These standards can be found on the Office of Environmental Information page of the EPA Internet web site under the *Collecting Environmental Information* heading and scrolling down to the Data Standards link (http://oaspub.epa.gov/edr/EPASTD$.STARTUP).

- Working closely with the Office of Water Information Resources Management Team and the Office of Environmental Information on all phases of system development, improvements, and updates.

Senior management and information system staff from all Office of Water programs coordinate and direct information system development, improvements and updates through participation on the Office of Water Information Steering Committee and the Office of Water Information Management Advisory Committee.

The goal of these efforts is to achieve *appropriate* levels of quality and consistency in the way data are generated, compiled, stored, and disseminated across all EPA water programs. This will ensure more complete and adequate data with which to make management decisions.

Compliance with Applicable Information System Standards

All efforts to develop, improve, or update information management systems within the Office of Water will comply with EPA Directive 2100, *Information Resources Management Policy Manual*. The efforts will include a systematic and comprehensive dialogue among the data providers, data and system users, and system developers, prior to the design of the system. The Office of Water relies on this directive and on other policies and guidance from the Office of Environmental Information to translate applicable Federal laws, Presidential Decision Directives and Memorandums, and Office of Management and Budget guidance into policy that the Office of Water can use to direct information systems development.

Highlights of the EPA directives and guidance that the Office of Water will follow for information systems development, operation, and improvement are identified below. The latest versions of these documents, as well as other applicable EPA policies, are available on EPA's Office of Environmental Information page on the Internet (http://www.epa.gov/irmpoli8/). Office of Water

personnel involved in information systems are required to familiarize themselves with this guidance and use any that is applicable to their efforts.

During the operational phases of any information management systems, Office of Water will comply with requirements within EPA Directive 2100 *Information Resources Management Policy Manual* and the most current version of the Office of Water *System Life Cycle Document*. Compliance with the applicable information resource management standards will ensure that all hardware and software configurations are tested prior to use, perform as expected, and meet user requirements.

- All information management system development, enhancement, and modernization efforts will comply with the most recent versions of the *System Design and Development Guidance* (EPA Directive 2182, April 30, 1993) and the *Operations and Maintenance Manual* (EPA Directive 2181, April 1990) available from the Office of Environmental Information.

- In addition, the Office of Water will comply with the *Delegation of Procurement Authority Guide* to ensure that purchased software will meet user requirements and will comply with the Office of Environmental Information standards.

- Managers and staff will comply with all hardware and software standards delineated in EPA's Information Technology Architecture Road Map. The road map establishes the Agency's information technology portfolio, as required under the Information Technology Management Reform Act of 1996. The road map forms the basis for the selection and deployment of supporting computing platforms and network connectivity between computing platforms, as well as the systems software and related products that interconnect computing platforms and make them operate.

The Office of Water also requires that sufficient data documentation be provided with a data set to assist potential data users when evaluating the utility of the data set for their purposes. This data documentation includes the original information on data quality associated with the data as well as any supplementary information on the direct application of the original data, known restrictions, or cautions which will facilitate the secondary use of the data.

Compliance with EPA Data Standards

The EPA Data Standards Program is established and documented in EPA Directive 2100 *Information Resources Management Policy Manual*. The Office of Water promotes the use of data standards to help information managers and the public assess environmental information more quickly and accurately, improve data sharing with stakeholders, maximize the use of resources and improve data integrity. Within the Office of Water, adherence to data standards policy is accomplished through the application of the data standards published by the Office of Environmental Information and available on their web page (http://oaspub.epa.gov/edr/EPASTD$.STARTUP). Currently, the following data standards have been published by the Office of Environmental Information and are available on EPA's web site:

- Biological Taxonomy (final)
- Chemical Identification (final)
- Date (final)
- Facility Identification (final)
- Latitude/Longitude (final)
- SIC/NAICS (final)
- Enforcement/Compliance (under development)
- Geolocational (under development)
- Permitting (under development)
- Tribal Identifiers (under development)

The Office of Water will actively participate on EPA and intergovernmental committees and/or workgroups, that actively pursue the development of comparable data elements and formats for data used by EPA water programs.

Office-wide Data System Coordination and Oversight

The Office of Water Senior Information Resource Management Officer is responsible for the Office of Water compliance and implementation of all Agency information system standards and policies outlined above. The Senior Information Resource Management Officer coordinates and provides oversight of information system activities in the water program offices through the Office of Water Information Steering Committee and the Office of Water Information Management Advisory Committee.

The Office of Water Information Steering Committee is comprised of the Senior Information Resource Management Officer and senior managers from all Headquarters water program offices. The Information Steering Committee is responsible for overseeing and coordinating information management activities within the Office of Water. The Senior Information Resource Management Officer and the Information Steering Committee work together to ensure that the Office of Water information systems are developed, operated and improved in full compliance with applicable Agency information systems directives, policies and data standards.

EPA's information system and data standards directives and policies apply to all EPA organizations and personnel, including contractors, Senior Environmental Employee Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems for Office of Water and EPA.

Other Information Systems

Individual projects within the Office of Water may involve smaller, specialized, and often ad hoc, information systems that could include small databases, spreadsheets, and data entry tools. Many of these are based on commercially-available software and may only be employed for short periods. As such, the system design guidance, life cycle requirements, and other information system standards may not be applicable and may do little to ensure the quality of those systems. Therefore, under the graded approach, the project planning team and the Branch Chief (or Associate Division Director) are responsible for identifying when such "minor" information systems will be employed and documenting all efforts by the project staff to ensure their quality.

Chapter 9
Procurement and Financial Assistance

It is Office of Water policy that quality system requirements be explicitly addressed when acquiring items and/or services that may result in or relate to the collection and/or use of environmental data. This policy applies to procurements such as contracts, as well as to cooperative agreements, partnership agreements, grants to institutions of higher education, and other non-profit organizations, Tribes, States, and local governments, and interagency agreements. The following Federal regulations contain sections relating to quality management or quality systems:

- 48 CFR Part 46. Quality Assurance
- 40 CFR Part 30. Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
- 40 CFR Part 31. Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments
- 40 CFR Part 35. State and Local Assistance

In addition, there are other rules and regulations that apply to contracts and other forms of financial assistance, including grants, assistance agreements, performance partnership agreements, and interagency agreements, as described below.

Contracts

Contracts are used when the principal purpose of acquiring the service or item is for the direct benefit or use of EPA. Obtaining services through contracting constitutes the largest extramural activity of the Office of Water. The Office of Water conducts procurement functions in accordance with the Federal Acquisition Regulations (FAR), and generally accepted business practices for the acquisition process. The FAR was recently amended to address contract quality systems requirements on a government-wide basis. The new FAR contract clause at 52.246-11, *Higher-Level Contract Quality Requirement* (February 1999), as prescribed by FAR 46.311, allows a Federal agency to select a voluntary consensus standard as the basis for its quality requirements for contracts, and identifies ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as an acceptable standard.

Due to these FAR changes, EPAAR 1546.2, *Contract Quality Requirements* (March 1984), which is a quality regulation that applies only to EPA, was determined to be unnecessary and the pertinent requirements from EPAAR 1546.2 will be included in the EPA Directive 1900, *Contracts Management Manual* (CMM).

Office of Water program management staff and quality management staff play active roles in assisting the contract management staff in defining the quality system requirements for contracts. Contracts involving the collection of either primary or secondary environmental data will include requirements for the provision of a quality management plan and quality assurance project plans, or other appropriate quality system documentation.

The EPA Office of Acquisitions Management issued Procurement Policy Notice No. 01-02 in March 2001 that provides guidance for the use of these higher-level contract quality requirements. Notice 01-02 includes two attachments that provide directions for contracting officers and their representatives in the program offices (e.g., Project Officer and Work Assignment Managers), as well as quality system staff, and describe the process for determining the quality system requirements that must be included in contract acquisition packages. These two attachments are included in Attachment C of this quality management plan.

Office of Water quality system staff also will assist in the contracting process by evaluating quality system documentation submitted by contractors in response to either pre-award or post-award requirements. As noted in the *EPA 1900 -- Contracts Management Manual*, a member of the Office of Water quality system staff at the appropriate level will be a member of the Technical Evaluation Panel for procurements over $500,000, in cases where quality system requirements are applicable to the procurement. Quality Assurance Coordinators or Quality Assurance Officers from the relevant program will generally fulfill this role.

Quality management procedures are outlined in *Staying on Course - A Guide for OW Work Assignment Managers* (EPA 8-B-93-003). Final approval of deliverables and services is the responsibility of the EPA work assignment manager with possible assistance from quality system staff at the appropriate level within the Office of Water (e.g., the Quality Assurance Coordinator). Deliverables and services that do not meet established requirements shall be identified, documented, and corrected by the contractor.

Financial Assistance

Grants and Assistance Agreements

Assistance agreements are used to support or stimulate activities that are not principally for the direct benefit of EPA. If the project involves environmentally-related measurements or generation of either primary or secondary data, then the applicant/recipient must develop and implement a quality management system. *Grants* are assistance agreements where EPA has no substantial involvement in the project. *Cooperative agreements* are assistance agreements where EPA has substantial involvement in the project.

All assistance agreements originating within the Office of Water must meet established administrative and quality assurance requirements in the latest editions of the following:

- *Assistance Administration Manual*, EPA Directive 5700, 1984 Edition (or later);
- EPA Order 5700.1, Policy for Distinguishing Between Assistance and Acquisition, March 22, 1994
- EPA Order 5730.1, Policy and Procedures for Funding Assistance Agreements, January 21, 1994
- 40 CFR Part 30, Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
- 40 CFR Part 31, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments
- 40 CFR Part 35, State and Local Assistance

As stated in *Managing Your Financial Assistance Agreement* (EPA 202-B-94-001, May 1994), it is Agency policy that applicants are required to develop and implement quality management practices for all projects involving environmentally-related measurements or data generation. These practices consist of policies, procedures, specifications, standards, and documentation which will produce data of sufficient quality to meet project objectives and will minimize loss of data due to out-of-control conditions or malfunctions. If the applicant has an EPA-approved quality assurance project plan and it covers the project in the application, then they need only reference the plan in their application. The quality assurance project plan must be acceptable to the Award Official in order to receive a grant award.

In keeping with the graded approach described throughout this plan, Office of Water policy requires that all parties receiving EPA grants/financial assistance under which environmental measurements (primary or secondary data) are performed include either a quality assurance project plan that has been prepared in accordance with *EPA Requirements for Quality Assurance Project Plans (Final, March 2001)*, or equivalent quality system documentation. The level of documentation must be established by Office of Water staff when planning for the grant or financial assistance.

The grant applicant is responsible for preparing the quality system documentation, which is then reviewed and certified by the Quality Assurance Officer or his designee before environmental measurements (primary or secondary data) are taken. For financial assistance grants under the purview of Regions, the Regional Quality Assurance Officer or his designee is responsible for the review and approval of the quality system documentation. At the request of the Regional Quality Assurance Officer, the quality system documentation also may be reviewed and cosigned by the Office of Water Quality Assurance Officer.

If an applicant is unfamiliar with EPA and the Office of Water quality requirements, the project officer should direct them to the appropriate quality staff, either in the Office of Water, or in the Office of Environmental Information. The following are quality requirements by applicant type:

- If an application is for research financial assistance, the application must include a quality statement which either addresses certain areas or provides justification why specific areas do not apply [see 40 C*FR* 30.54].

- If an application is from a State or Tribal government (except for a wastewater treatment construction grant) the applicant must define their plans for completion of the necessary quality system documentation [see 40 C*FR* 31.45].

- All other applicants must submit quality system documentation with their application.

The applicant's quality system documentation shall indicate whether the assistance involves an environmental data generation or use. A description of the program or project associated with the assistance is provided with Standard Form 424. The description contains 5 parts:

1. Objective
2. Results or Benefits Expected
3. Approach
4. General Program/Project Information
5. Quality Assurance Requirement

The decision on whether a grant or cooperative agreement involves environmental data generation or use is determined by the Office of Water Project Manager in consultation with the Quality Assurance Officer and a review of the narrative description provided with the Standard Form 424. The *Programmatic Certification-Authorization to Award an Assistance Agreement* form is signed and dated by the Office of Water Project Manager.

All applicants for grants or cooperative agreements involving environmental programs shall submit quality system documentation which describes the quality system implemented by the applicant, which may be in the form of a quality management plan or equivalent documentation.

The applicant’s quality system documentation will be reviewed and approved as a condition for award of any assistance agreement. The quality system documentation must be submitted as part of the application. If the quality system documentation is not submitted as part of the application and the Office of Water decides to fund the project, then the Office of Water will include a term and condition in the assistance agreement. This term and condition requires the recipient to submit the quality system documentation within a specified time after award of the agreement and notifies the recipient that they may not begin work involving environmental programs until the Office of Water Project Manager informs them that the quality system documentation has been approved.

Performance Partnership Agreements

When States receiving funds from the Office of Water agree to enter into performance partnership agreements with the Office of Water, the performance partnership agreements will be used as a mechanism to define the quality system requirements for the effort and to establish the respective roles of and responsibilities of the State and the Office of Water in quality management activities.

Interagency Agreements

Interagency agreements that are funded by the Office of Water should include quality system documentation requirements in the agreement. Because the Office of Water cannot unilaterally impose such requirements, these requirements must be negotiated into each agreement. Policies and administrative procedures governing interagency agreements are defined in Chapter 5 of *Managing Your Financial Assistance Agreement*. The Office of Water quality system requirements related to environmental data apply to all activities funded by the Office of Water through interagency agreements. Cooperative agreements that will produce environmental measurements must adhere to the quality system documentation requirements in 40 C*FR* 30.503. These standards must be included explicitly in all cooperative funding agreements.

All interagency agreements with environmental measurement activities which the Office of Water funds, or participates in, will include quality system documentation. Where the Office of Water is providing funds to another organization, that organization is responsible for preparing the quality system documentation. If the other organization has equivalent requirements for quality system documentation, that guidance may be employed. If there are not comparable quality system procedures, the quality system procedures agreeable to both parties must be negotiated prior to initiation of the program or effort and are attached to the Memorandum of Decision. The quality system documentation will be reviewed and certified by the appropriate the Office of Water Quality Assurance Officer before environmental measurements (primary or secondary data) are collected. All proposed cooperative funding agreements shall be reviewed to determine the applicability of quality system requirements as defined in EPA Order 5360.1 A2. This determination shall be documented by the Office of Water quality system staff within the Program Office providing the funding.

Where a quality management plan is required, the plan shall be prepared in accordance with the specifications provided in the most current version of *EPA Requirements for Quality Management Plans* (QA/R-2), which describes the quality system implemented by the party involved in the environmental program. The plan shall define the approving officials of the plan, which, at a minimum will be the Office of Water Quality Assurance Manager.

References

The EPA Quality Staff developed a series of documents describing the various requirements of the overall EPA quality system as well as a series of guidance documents that describe how the system can be implemented by EPA and by external organizations, including contractors and grantees. Many of these documents are cited in the body of this quality management plan. All of the documents are available from the Quality Staff web site in PDF format. The current uniform resource locator (URL) for that web site is: www.epa.gov/quality

The Quality Staff also are working on a variety of new documents and revisions to existing ones, and the reader is encouraged to check the web site above frequently for the latest available information.

Requirements Documents

All of the documents that describe formal quality requirements for EPA organizations are defined "EPA Directives," and are policy documents. These include:

- EPA Order 5360.1 A2, May 2000, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*. This document describes the Quality requirements for EPA organizations that produce environmental data.

- EPA Manual 5360 A1, May 2000, *EPA Quality Manual for Environmental Programs*. This document describes the specifications for satisfying the mandatory quality system defined in EPA Order 5360.1

Additional requirements documents apply to both EPA and external organizations. They are designated with the letter "R" followed by a number. The documents that are available in final form at this time are:

- EPA QA/R-2, March 2001, *EPA Requirements for Quality Management Plans*. QA/R-2 is the policy document containing the specifications and requirements for Quality Management Plans.

- EPA QA/R-5, March 2001, *EPA Requirements for Quality Assurance Project Plans*. QA/R-5 replaces the 1980 document QAMS-005/80. This external policy document establishes the requirements for QA Project Plans prepared for activities conducted by or funded by EPA. It is intended for use by organizations having extramural agreements with EPA.

Guidance Documents

The Quality Staff have prepared a number of guidance documents that can assist in the development and implementation of a suitable quality system for both EPA and non-EPA organizations. The guidance documents are designated with the letter "G" followed by a number. The documents that are available in final form at this time are:

- EPA QA/G-4, August 2000, *Guidance for the Data Quality Objectives Process*. QA/G-4 provides guidance to help organizations plan, implement, and evaluate the Data Quality Objectives (DQO) process, a systematic planning process for environmental data collection. It has a focus on environmental decision-making for regulatory and enforcement decisions. The guidance presents a step-by-step description of the DQO process.

- EPA QA/G-4D, September 1994, Data Quality Objectives Decision Errors Feasibility Trials (DEFT) Software. QA/G-4D provides guidance for using the Decision Error Feasibility Trials (DEFT) software to help organizations plan, implement, and evaluate the Data Quality Objectives (DQO) process. The guidance presents a step-by-step description of the use of the PC-based DEFT software DQO process.

- EPA QA/G-4HW, January 2000, *Guidance for the Data Quality Objectives Process for Hazardous Sites*. QA/G-4HW provides guidance to help organizations plan, implement, and evaluate the statistics-based Data Quality Objectives (DQO) process as applied to hazardous waste sampling activities. The guidance will present a step-by-step description of the DQO process and its application to environmental remediation and waste management activities.

- EPA QA/G-5, February 1998, *Guidance on Quality Assurance Project Plans*. QA/G-5 provides guidance to help organizations develop Quality Assurance Project Plans that will meet EPA expectations and requirements. The document provides a linkage between the DQO process and the QAPP. It contains tips, advice, and case studies to help users develop improved QAPPs.

- EPA QA/G-6, March 2001, Guidance for the Preparation of Operating Procedures for Quality-Related Operations. QA/G-6 provides guidance to help organizations develop and document standard operating procedures (SOPs). The document contains tips, advice, and case studies to help users develop improved SOPs.

- EPA QA/G-7, January 2000, *Guidance on Technical Assessments for Environmental Data Operations*. QA/G-7 provides guidance to help organizations plan, conduct, evaluate, and document technical assessments for their programs.

- EPA QA/G-9, July 2000, *Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis*. QA/G-9 provides guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations. Data quality assessment is a statistically-based, quantitative evaluation of the extent to which a data set satisfies the user's needs. This document is aimed at the project managers who are responsible for conducting the environmental data operations and assessing the usability of the results.

- EPA QA/G-9D, December 1997, *Data Quality Evaluation Statistical Toolbox (DataQUEST)*. QA/G-9D provides guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations using the PC-based software, DataQUEST.

- EPA QA/G-10, December 2000, Guidance for Determining Quality Training Requirements for Environmental Data Operations. QA/G-10 provides guidance to help organizations determine and develop program-specific quality system training for all levels of management and staff.

- No number, July 1999, *Guidance on Quality Assurance Project Plans for Secondary Research Data*. Example Quality Assurance Project Plan requirements for secondary research data developed by the QA Managers in EPA's National Risk Management Research Laboratory.

Attachment A

Office of Water Project Quality System Documentation Checklist

The purpose of this checklist is to guide EPA project managers, line managers, and quality system staff through the processes of planning a project, reviewing the planning documentation, and complying with the Office of Water quality system requirements for in-house work efforts, work assignments, contracts, cooperative agreements, grants, or interagency agreements where the Office of Water provides funds or technical support. As noted in Chapter 5, other forms of documentation may be employed, provided that the information needed to meet the requirements of the Office of Water quality system is included.

Office of Water Project Quality System Documentation Checklist
July 2001

The purpose of this checklist is to guide EPA project managers, line managers, and quality system staff through the processes of planning a project, reviewing the planning documentation, and complying with the Office of Water quality system requirements. Complete this form, or equivalent documentation, for any IN-HOUSE work effort, WORK ASSIGNMENT, CONTRACT, COOPERATIVE AGREEMENT, GRANT, or INTERAGENCY AGREEMENT where the Office of Water provides funds or technical support.

Section 1 - General Project Information - *(to be completed by the project manager or designee*)

Brief Descriptive Project Title:

Project Start Date:

Anticipated Project Completion Date:

EPA Project Manager:

Project Team Members:

Designated Quality System Team Member:

Name of contractor or grantee (if any):

Yes	**No**	
		Is this project related to a specific environmental decision, regulation, or enforcement action?
		Will EPA be collecting data during this project?
		Will an EPA contractor or grantee be collecting data during this project?
		Will data from other sources be used during this project?
		If so, were the data collected in association with this project or for some other purpose? (e.g., is this a secondary use of the data?)
		Sources of other data (if any):
		Is this a software/modeling development project?
		Is this a new contract, new work assignment, or new grant?

If the answer to **any** question above is "**Yes**," then complete the rest of this form.

If **all** answers above are "**No**," then sign this page and submit it with the procurement request or procurement initiation notice.

Project Manager's Signature **Date**

Section 2 - Documenting the Planning Process *(to be completed by the project manager in consultation with the project team, including the quality system member, e.g., the QAC)*

The Office of Water quality system requires the use of systematic planning for all projects. **Check off** each planning step that has been completed.

	Identify the customer(s) or stakeholders and their needs and expectations, for the results of the work to be performed. This includes identifying the project goal, objectives, and questions and issues to be addressed. Identify the technical and quality goals that meet their needs and expectations.
	Identify the applicable standards, specifications, and statutory requirements with which the project must comply, as well as any other societal implications.
	Consider and address potential risks (e.g., budget overrun) and tolerable error (quantitative or qualitative) based on consideration of their consequences, such as making incorrect interpretations or wrong decisions. Consider and address the impacts and consequences of uncertainty (lack of knowledge) and variability.
	Identify the steps that will be used to establish quality (e.g., independent review, in-process and final inspection and testing, precision, accuracy, QC samples, data quality assessment, level of detail in documentation, document and record retention requirements, validation and verification of data, audits, and assessments) and any needed reports (e.g., test, assessment, deficiency).
	Identify if peer review is required and when it will be conducted (e.g., now or later). All major scientific and technical work products used in decision making will be peer reviewed. These products are documents or positions that are used to support a research agenda, regulatory program, policy position or other Agency position or action. The "Managers Planning Checklist for Peer Review" in the Peer Review Handbook will assist you.
	Consider any cost and schedule constraints within which project activities must be performed.
	Consider acceptance criteria for the result or measures of performance by which the results will be evaluated and customer satisfaction will be determined.
	Translate the technical and quality goals and requirements into requirements or specifications for the work assignment, IAG, grant, or cooperative agreement. Use a graded approach based on the intended use of the results, the degree of confidence needed in the quality of the results, the importance of the project, the available resources, and the schedule.
	For any project involving environmental data, define and document the acceptance criteria or quality objectives (DQOs) necessary to meet the project objectives. State how the acceptance criteria will be developed, or if the formal DQO process will be used. State the type of quality system documentation that will be employed (e.g., a QAPP or other form), and specify who will review and approve the documentation.

Project Manager's Signature **Date** **Quality System Signature** **Date**

Section 3 - Quality System Documentation Requirements
(for projects involving environmental measurements)

The questions below are to be answered by the quality system staff member, e.g., the QAC, in order to establish the requirements for quality system documentation for the project.

Yes	No	Does the project require that:
		A written quality management plan or other document that describes the commitment of the Offeror's management to meet the quality requirements of the scope of work be included in the project plan, contract/cooperative agreement/grant proposal, etc.?
		A written quality assurance project plan (QAPP) be delivered as part of the project plan, contract proposal, grant, contract task order, etc.?
		Quality system reports be delivered? ___ with Progress Reports ___ with Final Report?
		Quality system audits be conducted for the contract? ___ Pre-Award ___ During Contract?
		Procedures are in place to review data against acceptance criteria?
		Another form of documentation be used instead of a QAPP (see below)?

Rationale, if no QAPP required: *(if another form of documentation is used, please specify it here)*

Please identify:

Organization responsible for preparing the QAPP or other quality system documentation _____

If EPA, name of author _____

Due date for QAPP or other documentation _____

Anticipated start date of data collection _____

Section 4 - Review and Approval of Quality System Documentation
(to be completed by the quality system member)

EPA reviewer for QAPP or other documentation _____

Date review completed _____

Date documentation approved _____

Location of approved and signed documentation _____

Project Manager's Signature **Date** **Quality System Signature** **Date**

Section 5 - Management Review *(to be completed by the Branch Chief in consultation with the quality system member)*

Yes	No	
		Are environmental data required for this project? (Section 1)
		Has the planning process been documented? (Section 2)
		Have requirements for the quality system documentation been established? (Section 3)
		Has the quality system documentation been reviewed and approved by both the Project Manager and the quality system staff member? (Section 4)
		If this is a contract, work assignment, task order, grant, cooperative agreement, or IAG, have the quality system requirements been included in the activity and documented on the appropriate forms?
		May this project proceed as planned?
		Is concurrence required from the Division Director or Office Director?

Comments:

Branch Chief's Signature **Date**

For projects at the Division level:

Division Director's Signature **Date**

For projects at the Office level:

Office Director's Signature **Date**

Attachment B

Generic Quality Assurance Project Plan Checklist

The checklist that follows is an example of an approach that can be used to evaluate quality assurance project plans developed by EPA or external organizations. It outlines 24 elements of a quality assurance project plan and asks questions about how the plan addresses various aspects of each element.

Under the graded approach to quality management described throughout this document, this checklist may be used as is, noting that aspects and elements that do not apply to a given environmental data collection project, or the checklist may be modified for project-specific needs. As noted in Chapter 5, other forms of documentation may be employed, provided that the information needed to meet the requirements of the Office of Water quality system is included.

Generic Quality Assurance Project Plan Checklist

July 2001

Project Title: **Reviewer:**

EPA Project Manager: **Date Submitted:**

Plan Author/Organization: **Date Reviewed:**

Conclusion/Recommendation:

Acceptable _____ **Acceptable with minor revisions** _____ **Not acceptable** _____

For plans found to be not acceptable, major deficiencies (defined here as the absence of relevant information) were found in the following elements:

___ Title & Approval Sheet
___ Table of Contents
___ Distribution List
___ Project/Task Organization
___ Problem Definition/Background
___ Project/Task Description
___ Quality Objectives & Criteria
___ Special Training/Certification
___ Documentation & Records
___ Sampling Process Design
___ Sampling Method
___ Sample Handling & Custody
___ Analytical Methods
___ Quality Control
___ Instrument/Equipment Testing
___ Instrument Calibration & Frequency
___ Inspection/Acceptance for Supplies
___ Data Acquisition (Non-Direct)
___ Data Management
___ Assessments & Response Actions
___ Reports to Management
___ Data Review, Validation, & Verification
___ Validation and Verification Methods
___ Reconciliation with User Requirements

See the attached sheets for comments related to all elements.

A = Acceptable NI = Not Included U = Unacceptable NA = Not Applicable	A	U	NI	NA	Comments
A1. Title & Approval Sheet					
Title					
Organization's name					
Dated signature of project manager					
Dated signature of QA officer					
Other signatures, as needed					
A2. Table of Contents					
A3. Distribution List					
A4. Project/Task Organization					
Identifies key individuals with their responsibilities (e.g., data users, decision makers, project QA manager, Subcontractors)					
Organization chart shows lines of authority & reporting responsibilities					
A5. Problem Definition/Background					
Clearly states problem or decision to be resolved					
Historical & background information					
A6. Project/Task Description					
Lists measurements to be made					
Cites applicable technical, regulatory, or program-specific quality standards, criteria, or objectives					
Notes special personnel or equipment requirements					
Provides work schedule					
Notes required project & QA records/reports					
A7. Quality Objectives & Criteria for Measurement Data					
States project objectives and limits, both qualitatively & quantitatively					
States & characterizes measurement quality objectives as to applicable action levels or criteria					
A8. Special Training Requirements/Certifications					
A9. Documentation & Records					
Lists information & records to be included in data report (e.g. raw data, field logs, results of QC checks, problems encountered)					
States requested lab turnaround time					
Gives retention time and location for records and reports					

A = Acceptable NI = Not Included U = Unacceptable NA = Not Applicable	A	U	NI	NA	Comments
B1. Sampling Process Design (Experimental Design)					
Types and number of samples required					
Sampling network design & rationale for design					
Sampling locations & frequency of sampling					
Sample matrices					
Classification of each measurement parameter as either critical or needed for information only					
Validation study information, for non-standard situations					
B2. Sampling Method Requirements					
Identifies sample collection procedures & methods					
Lists equipment needs					
Identifies support facilities					
Identifies individuals responsible for corrective action					
B3. Sample Handling & Custody Requirements					
Notes sample handling requirements					
Notes chain of custody procedures, if required					
B4. Analytical Methods Requirements					
Identifies analytical methods to be followed (with all options) & required equipment					
Provides validation information for non-standard methods					
Identifies individuals responsible for corrective action					
B5. Quality Control Requirements					
Identifies QC procedures & frequency for each sampling, analysis, or measurement technique, as well as associated acceptance criteria and corrective action					
References procedures used to calculate QC statistics (e.g., precision, bias, accuracy)					
B6. Instrument/Equipment Testing, Inspection, and Maintenance Requirements					
Identifies acceptance testing of sampling and measurement systems					
Describes equipment needing calibration and frequency for such calibration					
Notes availability & location of spare parts					

A = Acceptable NI = Not Included U = Unacceptable NA = Not Applicable **B7. Instrument Calibration & Frequency**	A	U	NI	NA	Comments
Identifies equipment needing calibration and frequency for such calibration					
Notes required calibration standards and/or equipment					
Cites calibration records & manner traceable to equipment					
B8. Inspection/Acceptance Requirements for Supplies & Consumables					
States acceptance criteria for supplies & consumables					
Notes responsible individuals					
B9. Data Acquisition Requirements for Non-Direct Measurements					
Identifies type of data needed from non-measurement sources (e.g., computer data bases and literature files), along with acceptance criteria for their use					
Describes any limitations of such data					
B10. Data Management					
Describes standard record keeping & data storage and retrieval requirements					
Checklist or standard forms attached to QAPP					
Describes data handling equipment & procedures used to process, compile and analyze data (e.g., required computer hardware & software)					

A = Acceptable NI = Not Included U = Unacceptable NA = Not Applicable	A	U	NI	NA	Comments
C1. Assessments & Response Actions					
Lists required number, frequency, & type of assessments, with approximate date & names of responsible personnel					
Identifies individuals responsible for corrective actions					
C2. Reports to Management					
Identifies the preparer and recipients of reports					
Identifies frequency and distribution of reports for:					
Project status					
Results of performance evaluations & audits					
Results of periodic data quality assessments					
Any significant QA problems					

A = Acceptable NI = Not Included **U = Unacceptable NA = Not Applicable**	**A**	**U**	**NI**	**NA**	**Comments**
D1. Data Review, Validation, & Verification					
States criteria for accepting, rejecting, or qualifying data					
Includes project-specific calculations or algorithms					
D2. Validation and Verification Methods					
Describes process for data validation and verification					
Identifies issue resolution procedure and responsible individuals					
Identifies method for conveying these results to data users					
D3. Reconciliation with User Requirements					
Describes process for reconciling with DQOs and reporting limitations on use of data					

Attachment C

The following pages contain two attachments to Procurement Policy Notice 01-02, issued by the EPA Office of Acquisition Management in March 2001.

To avoid confusion, these documents have *not* been renumbered for the purposes of this quality management plan, since they are the products of the Office of Acquisitions Management and are not subject to modification by the Office of Water. However, the titles of each document appears here with a parenthetical statement indicating their source, e.g., Procurement Policy Notice 01-02.

Attachment 1 (to Procurement Policy Notice 01-02)
Directions for Contracting Officer's Representatives

STEP 1. After consultation with the QA Manager (or the appropriate QA personnel[1]), complete the QA Review Form and obtain a concurrence signature of the QA Manager as part of the acquisition package. If QA requirements are not applicable to the procurement (indicated on the QA Review Form), the remaining Steps do not apply.

STEP 2. With the assistance of the QA Manager, determine what quality standards apply. Generally, ANSI/ASQC E4-1994 applies to the majority of EPA's work requiring higher-level contract quality requirements; however, standards other than ANSI/ASQC E4-1994 may also apply depending on the nature of the work (for example, ISO 9001, ANSI/ASME NQA-1, etc.). If ANSI/ASQC E4-1994 does not apply, proceed to Step 5.

STEP 3. If ANSI/ASQC E4-1994 applies, identify (with the assistance of the QA Manager) whether the contract work will consist of:

A. a single project - a contract in which there is one statement of work issued for a project that will occur only once;
B. multiple projects with different activities - a contract in which the statement of work contains multiple projects covering many different activities or tasks; for example, a contract to perform monitoring, sampling and analysis, data analysis, training, or other activities; or
C. multiple projects with similar activities - a contract in which the statement of work contains multiple projects covering similar activities or tasks; for example, a contract to perform monitoring that uses the same methodology at different locations.

A. If the contract consists of a ***single project***, you must require one of the following:

1. Before Award: A Quality Management Plan
   After Award: A Quality Assurance Project Plan for the contract
   (Note: These are the default requirements.)

2. Before Award: QA Manager-specified documentation[2]
   After Award: A Quality Management Plan and a Quality Assurance Project Plan for the contract

3. Before Award: QA Manager-specified documentation[2]
   After Award: A Joint Quality Management Plan/Quality Assurance Project Plan for the contract

[1]Appropriate QA personnel are defined in each EPA organization's Agency-approved Quality Management Plan. For simplicity, the use of the term QA Manager will refer to both the QA Manager and other approved QA personnel.

[2]QA Manager-specified documentation is defined in an EPA organization's Agency approved Quality Management Plan. This documentation must be consistent with Agency requirements defined in EPA Order 5360 A1 (May 2000).

4. Before Award: A Joint Quality Management Plan/Quality Assurance Project Plan for the contract
   After Award: None

B. If the contract consists of ***multiple projects with different activities***, you must require one of the following:

1. Before Award: A Quality Management Plan
   After Award: A Quality Assurance Project Plan for each applicable project
   (Note: These are the default requirements.)

2. Before Award: QA Manager-specified documentation[2]
   After Award: A Quality Management Plan and a Quality Assurance Project Plan for each applicable project

C. If the contract consists of ***multiple projects with similar activities***, you must require one of the following:

1. Before Award: A Quality Management Plan
   After Award: A Quality Assurance Project Plan for each applicable project
   (Note: These are the default requirements.)

2. Before Award: A Quality Management Plan
   After Award: A Programmatic Quality Assurance Project Plan for the entire program (contract) and a project-specific supplement to the Programmatic Quality Assurance Project Plan for each applicable project

3. Before Award: A Quality Management Plan and a Programmatic Quality Assurance Project Plan for the entire program (contract)
   After Award: A project-specific supplement to the Programmatic Quality Assurance Project Plan for each applicable project

4. Before Award: QA Manager-specified documentation[2]
   After Award: A Quality Management Plan and a Quality Assurance Project Plan for each applicable project

5. Before Award: QA Manager-specified documentation[2]
   After Award: A Quality Management Plan, a Programmatic Quality Assurance Project Plan for the entire program (contract), and a project-specific supplement to the Programmatic Quality Assurance Project Plan for each applicable project

For each of the three cases (single project, multiple projects with different activities, or multiple projects with similar activities), the default requirements are listed as the first option (1). These requirements should be used unless the QA Manager agrees to different requirements.

STEP 4. For each type of documentation selected in STEP 3, identify (with the assistance of the QA Manager) whether the documentation should be prepared in accordance with the standard EPA requirements [i.e., *EPA Requirements for Quality Management Plans (QA/R-2)* and *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*] or whether other EPA-approved requirements will be used. The standard EPA requirements should be used unless the QA Manager agrees to different requirements.

STEP 5. If additional standards were identified in Step 2, identify (with the assistance of the QA Manager) what documentation is required to determine conformance to these standards.

STEP 6. Provide the Contracting Officer with a list of the documentation required before and after award. Such information may be detailed in Attachment 2. It is recommended that you complete Attachment 2 and provide it to the Contracting Officer with the QA Review Form from STEP 1.

STEP 7. After award of the contract, if the work consists of multiple projects (cases B and C in STEP 3), complete a QA Review Form and Section 2 of Attachment 2 for each project and attach it to the project's statement of work (e.g., work assignment, delivery order, task order).

If a project requires quality documentation (for example, a project-specific supplement to the Programmatic Quality Assurance Project Plan), incorporate the requirement to develop this documentation and to implement the EPA-approved documentation into the project's statement of work. If the project will be based on previously prepared and current EPA-approved quality documentation[3], incorporate the requirement to implement this documentation into the project's statement of work and note this on the QA Review Form.

[3]For policy on approval procedures and requirements for ensuring quality documentation is current, see Sections 5.2.1 and 5.2.2 of EPA Order 5360 A1 (May 2000) and your organization's Quality Management Plan.

Attachment 2 (to Procurement Policy Notice 01-02)
Contracting Officer's Representatives Form for Defining Contract Quality Requirements

Use this form to provide direction to the Contracting Officer on the quality assurance activities that are required in the solicitation and contract.

1. a. Select all documentation required **before award of the contract:**

	Documentation	Specifications
☐	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]
☐	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
☐	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
☐	Other Equivalent: _____	*[Insert specification]* _____

b. If the standard specifications do not apply, identify equivalent specifications: _____.

2. a. Select all documentation required **after award of the contract** or upon issuance of the specific work to be performed under the contract:

	Documentation	Specifications	Due After
☐	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]	Award of contract
☐	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Contract Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract

☐	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Quality Assurance Project Plan for each applicable project	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work
☐	Project-specific supplement to Programmatic Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work
☐	Other Equivalent: _____	*[Insert specification]* _____	*[Select one]* ☐ award of contract ☐ issuance of statement of work

b. If the standard specifications do not apply, identify equivalent specifications: _____.

3. List any additional quality standards besides *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4)* that apply:

Title: _____
Numbering: _____
Date: _____
Documentation required to determine conformance: _____
_____

Attachment D

The following pages contain the quality assurance review form for extramural projects such as contracts.

QUALITY ASSURANCE REVIEW FORM FOR EXTRAMURAL PROJECTS (CONTRACTS)

I. GENERAL INFORMATION

Descriptive Title: _____

Sponsoring Program Office: _____

Approximate Dollar Value: _____

Duration: _____

II. This contract requires environmental measurements _____ (YES) Complete form; _____(NO) sign form and submit with procurement request or procurement initiation notice.

III. Quality Assurance Requirements (Projects involving environmental measurements):

YES ____ NO ____ a. Submission of a written quality assurance (QA) program plan (commitment of the offeror's management to meet the QA requirements of the scope of work) is to be included in the contract proposal.

YES ____ NO ____ b. Submission of a written QA project plan is to be included in the contract proposal.

YES ____ NO ____ c. A written QA project plan is required as a part of the contract.

YES ____ NO ____ d. Performance on available audit samples or devices shall be required as part of the evaluation criteria (see list on the next page).

YES ____ NO ____ e. An on-site evaluation of the offeror's facilities will be made to ensure that a QA system is operational and exhibits the capability for successful completion of this project (see schedule on the next page).

YES ____ NO ____ f. QA reports will be required (see schedule on the next page).

IV. Determination (Projects involving environmental measurements)

Percentage of technical evaluation points assigned to QA _____.

PO estimate of percentage of cost allocated to environmental measures _____.

For each parameter measured attach a summary which provides the following information:

a. Is quality control reference sampling or device available?

b. Are there split samples for cross-comparison?

c. Is it required for pre-award?

d. Specify frequency during the contract.
QA System Audits are required: Pre-award _____; during the contract .

QA Reports are required: with Progress Reports _____ ; with the Final Report ____

The signatures below verify that the QA requirements have been established.

_____ _____
Project Officer Signature Date

_____ _____
Quality Assurance Officer Signature Date

Attachment E

The following page contains the work assignment review checklist from the EPA Contract Management Division in Cincinnati.

CMD-CINCINNATI WORK ASSIGNMENT REVIEW CHECKLIST 2/99

1. Contract number: _____ 2. WA number: _____
3. Independent government estimate (attach completed form)
4. WA title: _____
5. Does WA/WA amendment fall within scope of work of this contract? ☐Yes ☐ No
   Cite specific section and paragraph(s) of contract SOW: _____

6. To the best of your knowledge, will the work to be performed under this WA duplicate any work previously performed or currently being performed under any EPA contract? ☐Yes ☐ No

7. (a) Total LOE ordered to date (not including this current WA/WA Amendment): _____
   (b) Total LOE authorized to date under current term: _____
   (c) Does this WA/WA amendment require the exercising of quantity options? ☐Yes ☐ No
   (If so , attached justification)

8. (a) Are funds obligated in contract to support this WA? ☐Yes ☐ No
   (b) Is funding PR attached to support this WA? ☐ Yes ☐ No
   (c) Is WA funded by multiple appropriations? ☐ Yes ☐ No
   (d) If multiple appropriations, can accounts be identified with specific tasks?
   (if not, attach FMD approval for use multiple appropriations) ☐Yes ☐ No

9. Will all work (including deliverables) be completed during the current term? ☐Yes ☐ No
10. Has the contractor been instructed to begin work on this WA,
    prior to CO approval of WA, by anyone in the organization? ☐Yes ☐ No
11. Does the WA contemplate improvement to realty
    (repairs, alterations, modifications to real property?) ☐Yes ☐ No
12. Does WA require printing or duplication exceeding contract limitations? ☐Yes ☐ No
13. Does WA require videotaping or graphics support? ☐Yes ☐ No
14. Does WA contemplate development or maintenance of software,
    purchase of ADP equipment or ADP support services? Estimated Cost?
    (If yes, attach OIRM approval if not obtained at award) ☐Yes ☐ No
15. (a) Has program recommended subcontracting/consulting
    services to meet WA requirements? ☐Yes ☐ No
    (b) Has contractor been directed to use a particular source? ☐Yes ☐ No
16. Does this WA include any actual or potential conflict of interest? ☐Yes ☐ No
17. (a) Does WA contemplate personal services? ☐Yes ☐ No
    (b) Does WA contemplate inherently government functions? ☐Yes ☐ No
    (c) Does WA contemplate advisory and assistance services? (If yes,
    attach copy of approval or indicate that this was obtained at contract award) ☐Yes ☐ No
18. Does the WA/WA amendment require the contractor to purchase or lease
    (for more than two months) accountable property? ☐Yes ☐ No

19. Is EPA Form 1900-65, designation and appointment of Project Officer/Work
    Assignment Manager/Delivery Order Officer, completed and attached? ☐Yes ☐ No
20. Is CBI checklist attached? ☐Yes ☐ No
21. Is quality assurance project plan required from contractor? ☐Yes ☐ No

_____ _____

Request/WAM signature (Date) Project Officer signature (Date)